MTN-003 SSP Manual
Section 16
ACASI Users Manual

Version 1.4
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Prepared for:

MTN VOICE Sites

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MTN VOICE ACASI EQUIPMENT

Each participating VOICE study site has been provided with the following ACASI equipment:

- Touch screen ACASI computers (each equipped with a 2GB Secure Digital (SD) storage card) and chargers (touch screen computer)

- Designated ACASI laptop computer for Data Manager function and charger (data manager computer)

- USB portable data storage device ("USB key")

- Audio headphones

- Stylus

- One Extra battery for each ACASI computer (in case of brown outs at the site)

The above-listed equipment may be used for purposes of ACASI data collection and transfer only. The equipment should not be used for any other office, business, or leisure activities. No additional software should be installed on any of the computers and the computers should not be used for word processing, browsing the Internet, or any other application. No technical changes should be made to any of the equipment unless directed by ACASI support personnel at the Population Council or MTN Statistical and Data Management Center (SDMC) i.e. SCHARP.

In the event that the laptop battery loses power, the touch screen ACASI computers are configured to automatically power down and go into hibernation. In this state the laptop will save whatever is on the screen to disk. The depleted laptop battery can then be replaced with a charged battery and the unit can then be turned back on. After turning on the touch screen computer, the power-on security password (see p.6 item#3) will need to be entered, and then the laptop will display the screen as it was before going into hibernation. It is important to keep all touch screen laptop batteries charged and available for use so that they can be available during power outages.

Please note that if you flatten the screen over the keyboard, you will need to adjust the orientation of the display by clicking the Swivel button. This button is on the bottom of the display, to the left of the center, and has an icon that shows a landscape changing to portrait display.

ONLY the data manager computer can be connected to the internet, and only when uploading data to the SCHARP ATLAS portal. For computer security reasons, no touch screen computer should ever be connected to the internet.

Each participating study site must specify in its site specific data management standard operating procedures (SOPs) for MTN-003 (VOICE) where the above listed equipment will be securely stored and which study staff are authorized to access the equipment. Study staff designated as responsible for proper storage of the touch screen computers should perform the following daily maintenance tasks with each touch screen computer on each workday:

- Turn on the touch screen computer and enter a valid User ID (see below for more information on User IDs)

- Verify that the touch screen computer boots up properly and is functioning

- Verify that the assigned (labeled to match computer name) SD card has been inserted in the touch screen computer

- Verify that a stylus is present in the stylus slot of the touch screen computer

- Clean the touch screen computer screen with cloth. DO NOT use liquid cleanser or water

- Charge the touch screen computer and ensure the battery is full at the start of each work day (in case of unexpected brown outs)

At the end of each workday, after performing required data backup and transfer tasks, study staff designated as responsible for proper storage of the touch screen computers and the data manager computer should ensure that the computers have been properly turned off and plugged in to recharge the batteries. Place the computers in a secure, dry location until the next day of use.

MTN VOICE ACASI USER ID NUMBERS

Each participating VOICE study site has been provided three different types of User ID numbers to be assigned to study staff involved in collecting and transferring ACASI data, as follows:

- ACASI Administrator: persons responsible for administering ACASI interviews with study participants

- ACASI Computer data managers: persons responsible for performing ACASI data back-ups and transfers to the MTN SDMC (i.e. SCHARP)

- Investigator (or designee): persons responsible for carrying out duties of the Computer data manager should that person not be available

Each ACASI Computer data manager and Investigator is assigned his/her own unique ACASI Administrator ID, as well as his/her own unique Windows login and password. The Windows logins are used on the data manager computers.

User IDs will be assigned to study staff using assignment forms provided in sealed envelopes. As User IDs are assigned, each staff member assigned an ID must sign and date his/her assignment form to acknowledge receipt of his/her User ID. Signed original forms should be maintained with other MTN VOICE Essential Documents related to study staffing. A copy of each signed form should be provided to Barbara Mensch or Stan Mierzwa at the Population Council. Also contact Barbara Mensch (BMENSCH@popcouncil.org) or Stan Mierzwa (SMIERZWA@popcouncil.org) if additional User IDs are needed.

NOTES ON SECURITY:

- Study staff to whom ACASI User IDs are assigned should not share their User IDs or passwords with anyone else.

- Each staff member should always use the same User ID and password.

MTN VOICE ACASI ADMINISTRATOR REFERENCE

Refer to Appendix A for general guidelines on setting up the participants for the ACASI interview

Turning on the Touch-Screen Laptop Computer (Figure 1)

1. Open the cover and press the silver button to turn on the laptop.

2. Retrieve the stylus from the left side of the computer by pressing it until it pops out.

3. A few seconds after the computer has been turned on, you will see a picture of a lock, which indicates that you need to enter the password. The power-on security password is **dvd15**

Figure 1

Administrative Setup (Figure 2-Figure 9)

As the ACASI Administrator, you will be prompted to enter some information into the computer before the participant practice session and subsequent ACASI interview. There is no audio associated with entry of this information. Note: must use dropdown menu for questions below for data to be accepted.

You will be prompted to enter:

- Your Administrator ID
- The Participant ID number (PTID)
- The visit code
- The visit date
- The questionnaire language
- The participant's number of live births (per her self-report at the time of the ACASI interview)
- The participant's age (per her self-report at the time of the ACASI interview)
- The number of days the participant went to the market in the past seven days (per her self-report at the time of the ACASI interview)

The administrator should enter all required information using either the physical keyboard or the screen keyboard and the stylus or mouse. If you are using the screen keyboard and you need to enter a number, tap into the box that requires the number and the keyboard (Figure 2) should appear on the screen

Figure 2

Entering the Administrative Information

1. **Administrator ID (Figure 3)**: Each ACASI Administrator has been assigned an ACASI user ID. Enter this ID as your Administrator ID by tapping on the keyboard screen with the stylus (or clicking with the mouse) and then tapping the green Submit button. Your ID will be masked, since it also serves as a security procedure for accessing the program.

Figure 3
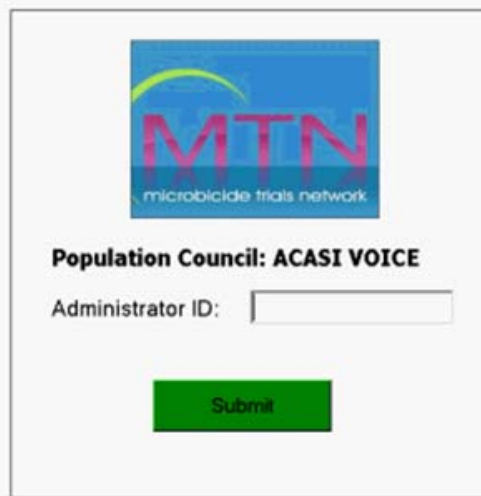
Administrator ID's assigned by country:

- 101 – 199   Uganda
- 200 - 299   Zimbabwe
- 300 – 499   South Africa
- 500 – 599   Malawi
- 600 – 699   Zambia

2. On the next screen, tap the **New Survey** button (Figure 4).

Figure 4

3. On the next screen (Figure 5) select the appropriate questionnaire by tapping the correct bar and then tapping the START SURVEY button.
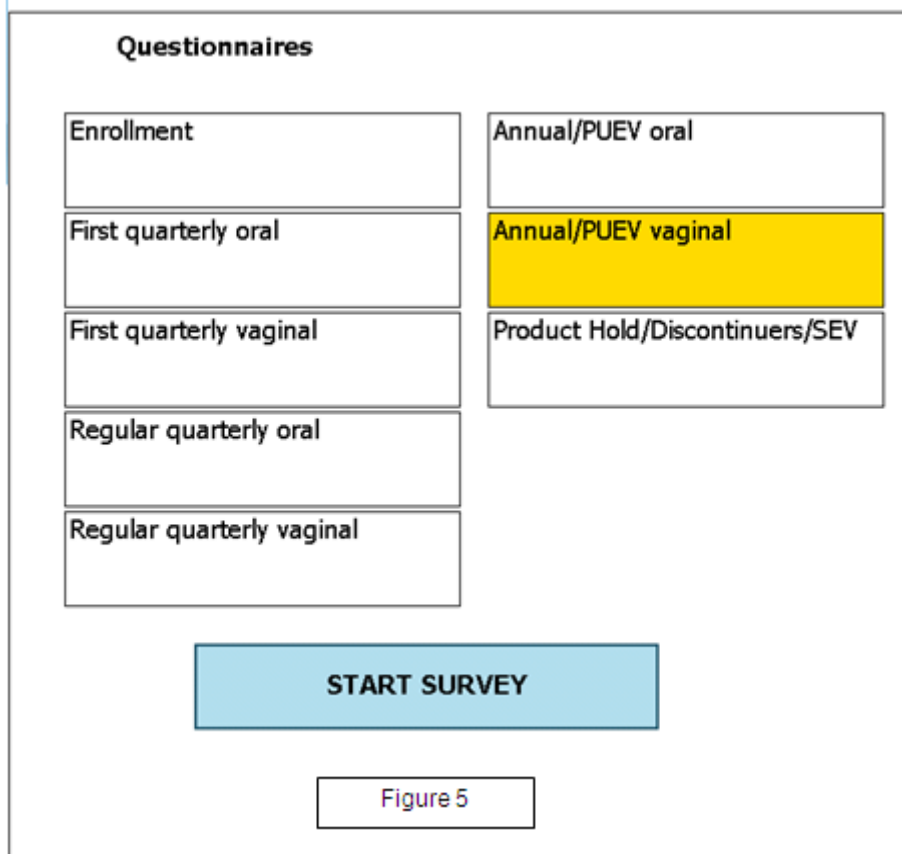

Figure 5

4. Enter the correct PTID in the Participant ID field (Figure 6). **NOTE**: If you entering test data, it is important that you enter one of the Test PTIDs listed in Appendix B of this document. Any Test PTID can be used, and Test PTIDs can be used more than once. Confirm that the correct PTID was entered by entering it a second time, and then tap the green Next button. In addition to confirming the PTID was entered in twice, when you click the green Next button, a check is made to ensure the PTID is valid as provided by SCHARP. If the PTID is not valid, you will be prompted to enter a valid PTID.

Figure 6

Figure 7

5. Select the correct visit code (Figure 7). You will select the appropriate visit code using the drop-down menus. Note that there is no built in validation for visit codes. It is the administrator's responsibility to ensure that the correct visit code is selected. When done, tap the green Next button.

6. Confirm the visit date (Figure 7). The visit date will be filled automatically using the numeric format dd/mm/yyyy (for example, 17/04/2009) but you must also confirm the visit date by selecting the appropriate two-digit day, three-character month, and 4-digit year from the drop-down menu.

7. Choose the appropriate ACASI language from the drop-down list (Figure 8).

8. Ask the participant how many children she had that were born alive and select that number from the pull down menu (Figure 8). Note: It is not necessary to obtain or verify the number of live births from the participant's study records. The number entered will have to match the number that will be entered for Practice Question 2 (PQ2)

9. Ask the participant how old she is and select the corresponding age range from the pull-down menu (Figure 8). It is not necessary to obtain or verify her age from the participant's study records The range entered will have to match the range entered in Practice Question 3 (PQ3)

10. Ask the participant on how many days she went to the market in the past 7 days and select that number from the pull down menu (Figure 8). The number entered will have to match the number entered for Practice Question 4 (PQ4)

Figure 8

11. After completing the above steps, tap the green Next button. A screen with a bar labeled "PRACTICE QUESTIONS" will appear (Figure 9). DO NOT tap the "PRACTICE QUESTIONS" bar until you have set up the participant for the interview and are ready to turn over the computer to her.

Figure 9

12. Turning the computer screen around

Before turning over the computer to the participant, you must turn the screen around as described below.

With one hand on the base/keyboard, use your other hand to twist the screen away from you to the left, in the direction of the arrow that you will see where the keyboard and display are connected.

Setting Up the Participant for the Interview

Refer to the ACASI training script on page 16 of this manual to set up the participant for the interview and begin the ACASI training session.

Audio-headphone training: Connect the headphones to the touch screen computer by plugging them into the green port. Ask the participant if she has ever used headphones before and show her how they work, including using the dial on the cable/wire to adjust the volume.

Show the participant how to put the headphones on. The side of the headphone labeled R should cover the right ear and the side labeled L, the left ear.

Stylus/touch screen training: The participant should be shown how to use the stylus – tap lightly and as straight as possible. For most questions participants may tap the black square, the red square, yellow square, numbered boxes, or a picture. If they tap on a picture, each tap will be counted towards the total for that question. She may tap up to 60 times for each question that involves a number. For instance, if she had four children, she would tap on the picture of the child four times.

Additional Instructions: Instruct the participant on the following:

- If she wants to change her answer to the previous question, she can tap the white (Previous) button. She can only go back to the question immediately preceding the current screen, after that, the previous button will be grayed out.

- If she has any other problems or would like to stop the interview for any reason, she should let you know. (Advise her on where to find you. You should be nearby so she can find you easily, but for privacy reasons you should not stay in the same room as the participant when she is doing her interview)

- If she would like to skip a question, the participant may press the small white circle in the center, at the bottom of the screen.

Practice Questions

Practice questions are to be conducted at Enrollment visit and First Quarterly Visit (at minimum), and any other visits as needed. After you have prepared the touch screen computer for the participant (steps 1-12 on page 6-10) and are ready to train the participant on how to use the computer using the practice questions, tap the "PRACTICE QUESTIONS" button to begin the practice questions. Refer to the ACASI training script on page 16 of this manual to begin the ACASI training session. You may want or need to review the practice questions multiple times with each participant during the training/practice session. One option is to go over the first practice question without earphones so as to provide guidance and explanation to the participant.

Sit next to the participant while she answers the practice questions.

There are five practice questions:

1. Are you a woman?
2. How many children have you given birth to who were alive at birth? (Figure 10)
3. What is your age?
4. In the past 7 days, on how many days did you go to the market?
5. The fifth practice screen is a set of questions which ask whether the participant has eaten a meal for each day in the past week (Figure 11)

The text of each question will appear on the computer screen in the language that is selected during the administrative setup and will be accompanied by an audio recording of the questions that the participant will hear through the headphones. The participant will need to provide the correct answer to each question in order to move to the next question.

Please note: the responses to the practice questions responses are not stored
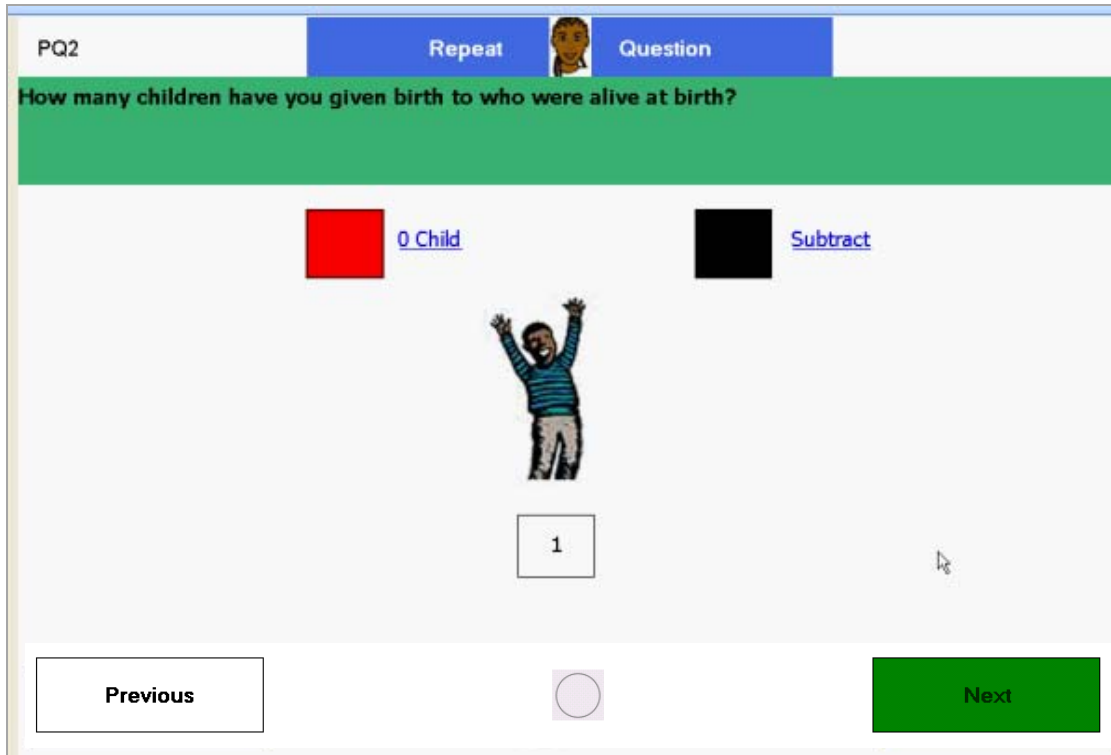

Figure 10
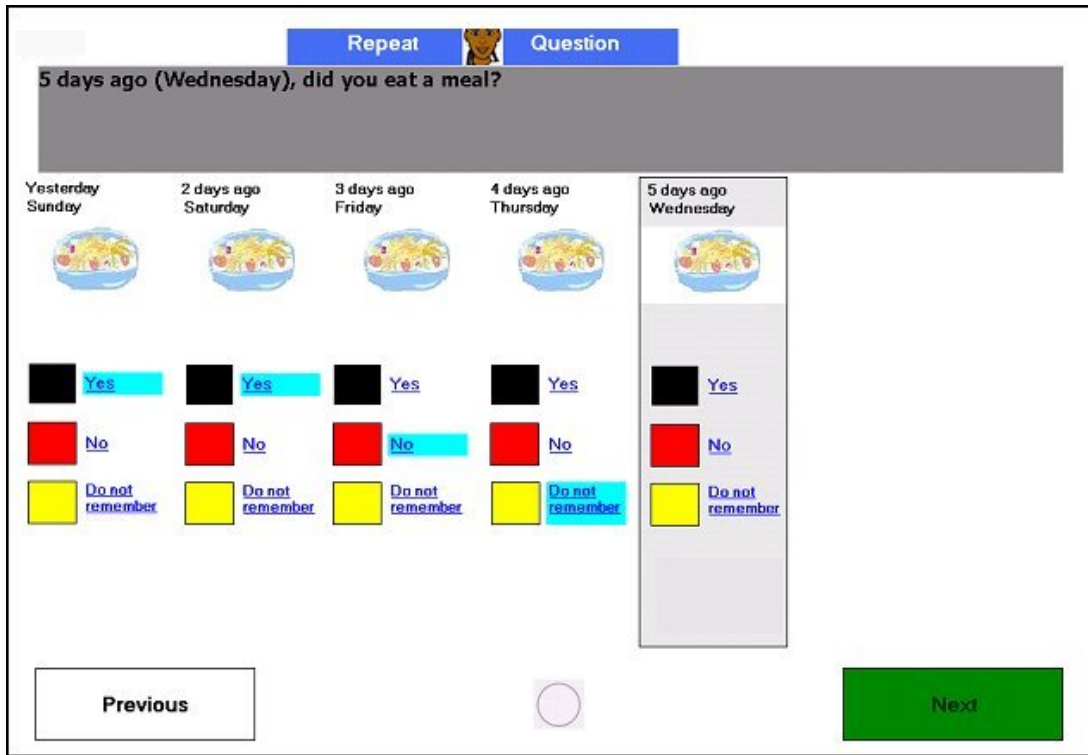
Figure 11

Once the participant has answered the practice questions, there will be 2 options (Figure 12):
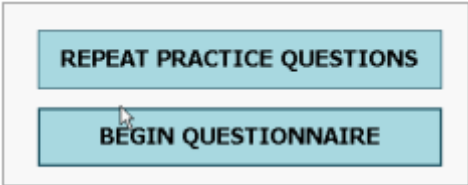
Figure 12

1) You can have the participants repeat the practice questions by tapping the "REPEAT PRACTICE QUESTIONS" button.

   Select this option if you think the participant needs more practice before beginning the MTN VOICE ACASI interview.

2) You can have the participant proceed to the MTN VOICE ACASI interview questions by tapping the "BEGIN QUESTIONNAIRE" button.

   Select this option if you think the participant is ready to proceed to the actual MTN VOICE ACASI interview questions. Before proceeding, one addition guidance point to explain to the participant is that while she hears some of the longer audio files which introduce sets of related questions, she will see a simple graphic such as the ones shown below (Figure 13).

Figure 13

Once the participant has completed the practice questions and begins the MTN VOICE ACASI interview, <u>you should leave the room</u>. You should however, wait outside the interview room so that you are available should the participants have any questions or problems.

Exiting the ACASI Program

At any time, you may terminate the interview application by double tapping or double clicking on the

top left corner of the screen where you see the small white square with a black border ☐ . A gray box will pop up, asking if you would like to exit the survey. During the administrative setup, you may double tap on the MTN logo to exit the program.

Please note, each time an interview is completed, the computer will automatically reboot and take you back to the initial login screen.

Things to Keep in Mind

- If the participant lacks numerical literacy, or if the participant is unable to correctly use ACASI after multiple attempts with practice questions, the participant should not complete the ACASI Enrollment Questionnaire. Document in the participant's chart notes that she is unable to complete the ACASI questionnaire and specify the reason(s). Mark the "no" box for item 4 on the Enrollment CRF and record the reason(s) the questionnaire was not completed. Have **another administrator** (if possible) conduct the practice questions with the participant at her first quarterly ACASI. If again , she is unable to use ACASI, repeat steps above. For more detailed information on procedures for this situation, refer to Data Communique #2 posted on the MTN website SSP Manual Section 15: http://www.mtnstopshiv.org/node/1077.

- There are internal checks built into some of the practice questions, this is by design. The responses must agree with each other, specifically for questions regarding the participant's age, number of children, and number of days she went to the market. She will be prompted to try the question again if the answer she gives during the practice questions does not agree with the answers that you entered in the administrative section.

- There are no validation checks for the visit code number entered by the administrator. Please make sure you double check that the correct visit code has been entered when completing the administrative section

- If there are any program or computer failures during an interview, please write down the question number and the context in which the error occurred. As much information as possible about the situation that brought about the error would be useful for correcting the problem. If the error causes the interview program to stop, you should exit the program and restart it.

- If an interview is terminated that is only partially completed, the participant will need to start from the beginning with a new interview. The interview program will allow one study participant to complete the interview more than once, but the data from each interview will be saved separately.

- If participant **misses her Month 3 Visit**, administer the First Quarterly Oral ACASI questionnaire at the first quarterly visit she completes. *The first quarterly ACASI questionnaire is the exception, no other type of ACASI questionnaire will be made up. This is because product sharing is asked in the first quarterly ACASI and then not again until her month 12 questionnaire. If a participant misses her first quarterly, waiting until Month 12 is too long to obtain data on product sharing.*

- If a participant **misses her Month 12 visit**, SKIP the annual ACASI questionnaire and administer the regular quarterly questionnaire at her next scheduled quarterly visit (i.e. her month 15 visit).

- You may need to respond to specific questions the participant may have about how to enter their response or about the interview questions. To answer questions related to how to use ACASI, please refer to the guide for administrators on how to use ACASI (pages 20-21). To answer specific questions on the meaning of the survey questions, please refer to the QxQ Guide (pages 22-34). Note that the majority of participant questions are expected to be about the content and meaning of the questions.

- As you remove the SD card from the touch screen laptop, you might move the gray tab on the left side of the card to the "locked" position. Before inserting the SD card into the Data Manager laptop, you must be sure that the card is unlocked by moving the gray tab back up to the unlocked position.
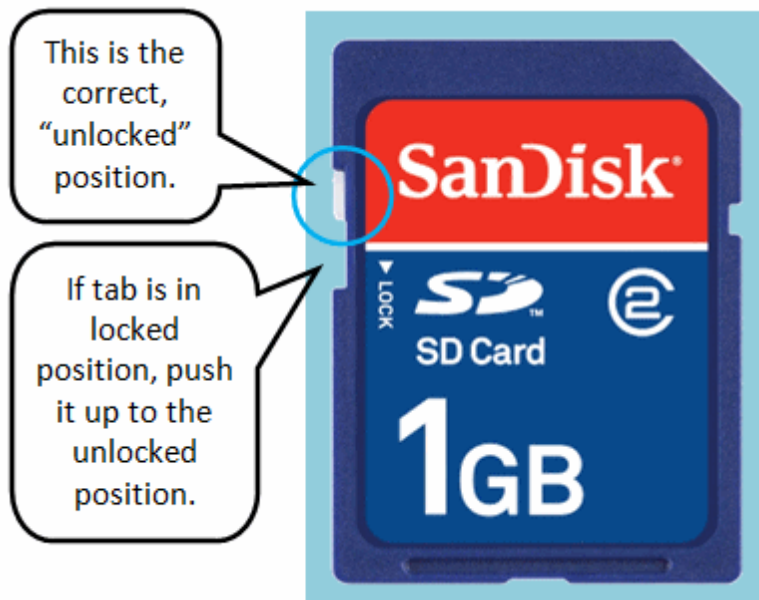
ACASI Training Script	
Sit next to the participant and use the following training script to show the participant how to use the touch screen computer, headphones and stylus. (Local language training scripts are available online as separate documents)	
MAIN TOPICS	**CONTENT**
INTRODUCE SELF AND INTERVIEW	Hello, my name is _____. I am going to set up the computer for your interview and show you how it works. If you have any questions at any time, please feel free to stop me and ask. We will work together until you feel comfortable using the computer on your own.
EXPLAIN CONFIDENTIALITY	I want you to know that your answers to these questions are confidential. That means your personal information will be kept private and will not be discussed with anyone else.
EXPLAIN AND DEMONSTRATE HEADPHONES	The interview questions have been recorded on the computer, so instead of me asking you the questions, you will hear them through the headphones. You place the headphones on your head like this [*show ppt*]. You can adjust the loudness of the voice you hear by turning this knob [*show ppt*]. Do you have any questions?
EXPLAIN HOW THE PARTICIPANT WILL HEAR AND SEE THE QUESTIONS	You will hear each question and the possible responses on your headphones. If you would like to answer the question before you have heard all of the possible responses, please feel free to do so. However, we ask you to take as much time as you need to think about the best answer to fit your situation. What you hear on the headphones is not "live" [explain more if needed] so you should not answer the questions out loud. Instead, I will show you how to answer the questions using this stylus [show the participant how to use the stylus].
IF PARTICIPANT IS LITERATE PLEASE ADD:	You can read the question at the same time, as it will also be displayed on the screen.
EXPLAIN AND DEMONSTRATE STYLUS	When you are asked a question, you will choose your answer by pressing the computer screen with the stylus. Press the screen lightly and as straight as possible. [*show ppt*]

EXPLAIN DIFFERENT WAYS TO RESPOND TO QUESTIONS:	Each question can have 2 to 6 possible responses. You select your response by pressing colored boxes, or a picture, or a box with a number in it.
COLORED BOXES	For example, if you are asked whether you are a female, there will be a red box next to "No" and a black box next to "Yes." You would press the red box if you are male and the black box if you are female.
PICTURES	
NUMBERED BOXES	For some questions, you may press a picture. If you press the picture, each tap will be included in the final tally for that question. The final tally you have entered will be read aloud by the computer.
SUBTRACTING	
ZERO	If you press more times than you meant to, you can press the black box to subtract from the tally.
	You will also be able to enter "0" for some questions by pressing the red box
	For other questions, you may press the box with the number corresponding to your answer for that question

EXPLAIN HOW TO ANSWER COUNT QUESTIONS	For Questions that prompt you to count, **press the picture** to provide the answer. Do not press the box below the picture. The box below the picture will show the number of times you have **pressed the picture**.
	If you press the picture too many times, press the black box to subtract from the total count.
EXPLAIN HOW TO ANSWER CALENDAR QUESTIONS	Calendar questions are for questions involving multiple days.
	For calendar questions, respond for each day by pressing the black box (yes), red box (no) or yellow box (do not remember) for that day. After you respond for that given day, press the **green box** at the bottom right of the screen to move to the next day, which will then be highlighted in a **gray highlighted box**. For each additional day, press the appropriate box (black, red or yellow) associated with that day highlighted in gray. Do not press again the box options for previous days you have already responded to, unless you want or need to correct your answers.

EXPLAIN HOW TO REPEAT A QUESTION	If you need to hear a question again, you may press the picture of the woman at the top of the screen with the stylus.

EXPLAIN HOW TO RETURN TO A PREVIOUS QUESTION	If you want to go back to the previous question, press the big white box at the bottom left of the computer.
PRACTICE QUESTION [PQ1] WITHOUT HEADPHONES	Let's try some practice questions together – the first question asks whether you are a woman. Press the black box once to confirm that you are. After you have answered the question, the computer will tell you to press the green box to go to the next question.
PRACTICE QUESTION [PQ2] WITHOUT HEADPHONES	Let's try another practice question. This question asks about your children. You have the option of choosing "0" by pressing the red box or by pressing the picture once for each child you had that was born alive. [*May be helpful to give example – "if you have four children, you would* press *the picture four times"*]. After you have entered the number of children you had, the computer will tell you to press the green box to go to the next question.
PRACTICE QUESTION [PQ3] WITHOUT HEADPHONES	Let's try another practice question. This question asks about your age and gives you four age ranges to choose from, including "don't know" and then the computer will tell you to press the green box to go to the next question. [*It may be helpful to give an example – "if you are 22 years old, you would* press *the box indicating 18-24"*] Please press the correct answer now. Do you understand?
PRACTICE QUESTION [PQ4] WITHOUT HEADPHONES	Here is another practice question. This question asks about the number of days you went to the market in the past 7 days. Here, you press the box corresponding to the number of days you went to the market in the past 7 days. For example, if you went to the market on two days, you will press the number 2 box.

PRACTICE QUESTION [PQ5] WITHOUT HEADPHONES	Let's try another practice question. This question asks about the meals you ate in the past week. Here, for each day, you have the option of choosing yes by pressing the black box, if you ate a meal on that day or choosing no by pressing the red box if you did not eat a meal on that day, or choosing "do not remember" by pressing the yellow box. After you respond for each day, you will press the **green box** to move to the next day which will then get highlighted in **gray**. After you have answered for all seven days, the computer will tell you to press the green box to go to the next question. If you need to correct your answer to one of the days, change it before you move to the next question (next screen), by tapping on the correct answer for that day (Show how answers for each day on the calendar can be changed while the calendar is "active" on the screen). Let's try with yesterday…Please press the correct answer now for yesterday. Do you understand?
REPEAT PRACTICE QUESTIONS WITH HEADPHONES	Let's try going through these practice questions again but this time with the headphones.
PAUSE SURVEY	You have done very well in learning how to use the computer and headphones. I think you are ready to now answer the interview questions on your own. Do you have any questions before you proceed? [*Discuss as needed*.] Now I'm going to leave the room so you can answer the questions in private. I will be sitting just outside the room if you have any questions. Please remember to take off your headphones and come get me when you are finished or if you have any questions during the interview.
LEAVE ROOM WHILE PARTICIPANT STARTS ACASI INTERVIEW	

Guide for Administrators: Instructions on how to use ACASI

1. If the participant has a question about **how to proceed from one question to the next** say

   "After answering each question, to go to the next question, press the big green box at the bottom

   right of the screen."

2. If the participant has a question about **how to hear a question again** say *"If you want to hear a*

   question again, press the picture of the woman at the top of the screen."

3. If the participant has a question about **how to go back to the previous question** say *"If you*

   want to go back to the previous question, press the big white box at the bottom left of the screen."

   If the participant asks for guidance on how to answer a question, it is important to guide her on how to answer the question using hypothetical answers. Do not ask her what answer she would like to enter. Below are specific instructions on how to answer participant's questions on how to answer a particular question

   If the participant has a question about **how to answer a count question with an image response** say *"If you have not done this, press the red box. If you have done this, press the picture one time for each time you have done this. For example, if you have done this once, press the picture one time. If you have done this twice, press two times, and so on. If you make a mistake and press the picture too many times, press the black box to decrease the number. If clarification is needed about the maximum number of times the picture can be pressed, you can say "the picture can be tapped up to 60 times. If you want to report an answer that is greater than 60, just tap the maximum number allowed (60)."*

4. *After you have answered, press the big green box at the bottom right of the screen to go to the*

   next question."

5. If the participant has a question about **how to answer a Yes/No question** say *"If your answer is*

   'yes', press the black box. If your answer is 'no', press the red box."

6. If the participant has a question about **how to answer a Yes/No/I don't know question** say *"If*

   you want to hear the instructions again, press the picture of the woman at the top of the screen.

   Listen to the choices that the computer gives you and press the colored box that corresponds

   with your answer. If your answer is 'yes', press the black box. If your answer is 'no', press the red

   box. If you don't know or don't remember, press the yellow box."

7. If the participant has a question about **how to answer a question with multiple colored boxes**

   say *"If you want to hear the instructions again, press the picture of the woman at the top of the*

   screen. Listen to the choices that the computer gives you and press the colored box that

   corresponds with your answer. For example, for the practice question that asked you about how

old you are, If you are between 18 and 24 years old, you would press the black box. If you are

between 25 and 34 years old, you would press the red box. If you are 35 or older, you would

press the yellow box. If you don't know, you would press the white box."

8. If the participant has a question about **how to answer a question with numbered responses** say *"If you want to hear the instructions again, press the picture of the woman at the top of the screen. Listen to the choices that the computer gives you and press the box corresponding to the number of times that you did what the computer is asking. For example, if your answer is 2, you would press the number 2 box.*

9. For the calendar, if the participant says she doesn't remember which days she did something say *"We are most interested in knowing on how many days you did or did not do this. If you cannot remember on which day(s) you did and which days you didn't do this, please guess as we would like to know the number of days even if you are guessing which days.*

10. If the participant has a question about how to answer a **question on the daily retrospective calendar** say*, "If you did this on this day, press the black box. If you did not do this press the red box. If you don't remember, press the yellow box."*

After you respond for each day, press the green box to move to the next day. You will see that you have properly moved onto the next day by seeing it highlighted in **gray**. Respond to the box options for the day highlighted in **gray, then move to the next day**.

11. Special case: for participants who have been on a product hold or who permanently discontinued study product use, please refer to instructions in appendix F.

12. If a visit at which an ACASI interview is required is conducted as a split visit, the entire ACASI interview must be completed on one day. If an ACASI interview is begun, but not completed, on the first day of a split visit, the entire ACASI interview should be administered (starting from the beginning) on the second day of the split visit.

Guide for Administrators: Question by Question (QxQ)

Instructions on how to answer questions about the ACASI survey questions

Question #	Question	QXQ Instructions
	Sexual Partners	
1	Do you currently have a primary sex partner?	If clarification is needed, say "By primary sex partner, I mean a boyfriend, a husband, someone with whom you live, or a male sex partner that you are more serious about than other sex partners."
1a	Have you changed your primary sex partner in the past 3 months?	If clarification is needed, say "between now (early/mid/late [insert current month] and (early/mid/late [insert month that was three months ago] has the person who you consider to be your primary sex partner changed? By primary sex partner, I mean a boyfriend, husband, someone with whom you live, or a male sex partner that you are more serious about than other sex partners. For example, if the interview was being conducted in late January, the administrator would say "in the past three months, between late October and now, late January."
1b	Is your primary sex partner circumcised?	If clarification is needed, say "click on the image that most closely resembles your partner's penis"
2	Does your primary sex partner know that you are taking part in this study?	If clarification is needed, say "have you talked to your primary sex partner about your participation in this study?"
3T	Does your primary sex partner know that you are taking study tablets for this research study?	If clarification is needed, say "have you talked to your primary sex partner about taking study tablets for this research study?"
3G	Does your primary sex partner know that you are using study gel for this research study?	If clarification is needed, say "have you talked to your primary sex partner about using study gel for this research study?"

Question #	Question	QXQ Instructions
4	Does anyone with HIV/AIDS live in your household?	If clarification is needed say "to the best of your knowledge is there anyone who lives in your house who is infected with the HIV virus or who has AIDS?"
5	As far as you know, does your primary sex partner have HIV/AIDS?	If clarification is needed, say "By primary sex partner, I mean a boyfriend, a husband, someone with whom you live, or a male sex partner that you are more serious about than other sex partners." If further clarification is needed say "to the best of your knowledge is your primary sex partner infected with the HIV virus or does he have AIDS?"
6	How worried are you that your primary sex partner may get infected with HIV in the next year?	If clarification is needed, say "By primary sex partner, I mean a boyfriend, a husband, someone with whom you live, or a male sex partner that you are more serious about than other sex partners." If further clarification is needed say "thinking about the next 12 months between now and one year from now, how worried are you that your primary sex partner might become infected with the HIV virus during that time?"
7	How worried are you that you may get infected with HIV in the next year?	If clarification is needed, say "thinking about the next 12 months (between now and one year from now), how worried are you that you might become infected with the HIV virus during that time?
8	In the past 3 months, has your primary sex partner had sex with another partner besides you?	If clarification is needed about the time frame, say "by in the past 3 months, we mean between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]). If clarification is needed with regard to "another partner", say "In the past three months has your primary sex partner had sex with anyone else besides you?"" or "has he had other sexual partners?"

Question #	Question	QXQ Instructions
9	In the past 3 months, have you had vaginal sex with your primary sex partner?	If clarification is needed about the time frame, say "by 'in the past 3 months' we mean, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]). If clarification is needed with regard to the question say "By vaginal sex we mean when a male partner puts his penis inside of your vagina."
10	In the past 3 months, with how many other male partners have you had vaginal sex?	If clarification is needed about the time frame, say "by 'in the past 3 months' we mean, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month])." If clarification is needed about the question say "with how many men other than your primary sex partner have you had vaginal sex in the past 3 months?" This is a count question. If the participant has difficulty responding to a count question, read the specific instructions regarding count questions on page 20.
11	In the past 3 months how many times have you had anal sex?	If clarification is needed about the time frame, say "by 'in the past 3 months' we mean, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]). If clarification is needed with regard to the question say "By anal sex we mean when a man puts his penis inside your anus". This does not mean vaginal sex "from behind". 0 means none in the past 3 months but may translate awkwardly in some local language. There is a discrepancy between the audio and the text in the responses to this question. One of the text options is "7 times or more". The audio only says "7" however it means 7 times or more.
11a	During the last act of anal sex that you had, was a male condom used?	If clarification is needed, indicate that the last act could have happened TODAY. If clarification is needed about "last act of anal sex", say "by 'last act of anal sex', I mean 'last round of anal sex before today's interview'." NOTE: "Condom use" does not have a strict definition; rather, it is based on the participant's understanding of what "condom use" means to her. If questions arise or if condoms were used incompletely, say "your answer to this question should be based on your own judgment of whether or not you used a condom during anal sex."

Question #	Question	QXQ Instructions
12	In the past 3 months, on average, how often did you drink beer, wine, liquor, or other alcohol?	If clarification is needed about the time frame, say "by 'in the past 3 months' we mean, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month])." If clarification is needed say "take your best guess about how often you drank beer, wine, liquor, or other alcohol within the past three months." If participant only drank once or twice, she should respond "less than once a week"
	IVP Questions	Behavior outside of menses/menstrual period
13	When was the last time you put soap (with or without water) into your vagina?	If clarification is needed about what "put inside the vagina" means say "inserted inside the vagina." What is meant here is whether the woman used bathing soap either alone or with water <u>inside</u> her vagina. This does not include applying these to the external genitalia. This does not include household or laundry detergents.
14	When was the last time you put water only into your vagina?	If clarification is needed about what "put inside the vagina" means say "inserted inside the vagina." This could be when she is bathing or cleaning, and use water intravaginally. This does not include applying water to the external genitalia.
15	When was the last time you put paper, cloth, tissue, rags or cotton wool into your vagina?	If clarification is needed about what "put inside the vagina" means say "inserted inside the vagina." This does not include applying these products to the external genitalia. If clarification is needed about the type of items referred to in the question, say "Non-commercial items such as newspaper or other kinds of paper, tissue, toilet paper, rags, cloths or other kinds of absorbent materials."
20	In the past year, did you receive money, material goods, gifts, drugs, or shelter in exchange for vaginal or anal sex?	If clarification is needed about the time frame say "by 'in the past year' we mean in the past 12 months, between (insert current month, current year) and (insert current month, previous year)." If clarification is needed with regard to the question, say "in the past 12 months did you ever have transactional sex, or did you ever exchange vaginal or anal sex for food, gifts, drugs, or shelter."
	Recent Sexual Activity	

Question #	Question	QXQ Instructions
21	In the past 7 days, how many acts of vaginal sex did you have?	If clarification is needed indicate that the past 7 days do NOT include today. The interviewer can also say "in the last week, from last X [insert day of week 8 days ago] to YESTERDAY." If clarification is needed about "acts of vaginal sex", say "by 'acts of vaginal sex', I mean 'rounds of vaginal sex'." This is a count question. If the participant has difficulty responding to a count question, read the specific instructions regarding count questions on page 20.
21a	In the past 7 days, during how many acts of vaginal sex was a male or female condom used?	If clarification is needed indicate that the past 7 days do NOT include today. The interviewer can also say "in the last week, from last X [insert day of week 8 days ago] to YESTERDAY." If clarification is needed about "acts of vaginal sex", say "by 'acts of vaginal sex', I mean 'rounds of vaginal sex'." NOTE: "Condom use" does not have a strict definition; rather, it is based on the participant's understanding of what "condom use" means to her. If questions arise or if condoms were used incompletely, say "your answer to this question should be based on your own judgment of whether or not you used a condom during vaginal sex." This is a count question. If the participant has difficulty responding to a count question, read the specific instructions regarding count questions on page 20.
22	During the last act of vaginal sex that you had, was a male or female condom used?	If clarification is needed, indicate that the last act could have happened TODAY. If clarification is needed about "last act of vaginal sex", say "by 'last act of vaginal sex', I mean 'last round of vaginal sex' before today's interview." NOTE: "Condom use" does not have a strict definition; rather, it is based on the participant's understanding of what "condom use" means to her. If questions arise or if condoms were used incompletely, say "your answer to this question should be based on your own judgment of whether or not you used a condom during vaginal sex."

Question #	Question	QXQ Instructions
22a	During the last act of vaginal sex that you had, what type of condom was used?	If clarification is needed, indicate that the last act could have happened TODAY. If clarification is needed about "last act of vaginal sex", say "by 'last act of vaginal sex', I mean 'last round of vaginal sex' before today's interview." If clarification is needed about type of condoms, tell the participant to "click on the image of the condom that most resembles the condom that was used during the last act of vaginal sex that she had"
	Correct Condom use Q's	
22b	Did the condom break, slip, tear or spill	If clarification is needed say "was the condom damaged at all, or did it come off your partner's penis, during the last act of vaginal sex that you had?"
22c	Was the condom put on after penile penetration	If clarification is needed say "did your male partner put the condom on after he had already inserted his penis inside your vagina?"
22d	Was the condom taken off before ejaculation	If clarification is needed say "did your pale partner take the condom off before he "came" or before he "finished"?
	Study Product Use	
P24_1T	Please rate your ability, over the past 4 weeks, to take tablets exactly as you were instructed.	If clarification is needed say "This question is asking about the past 4 weeks, or in other words, the past 28 day," If further clarification is needed, say " In the past 4 weeks, how well were you able to take your tablets exactly as you were told by study staff?"
P24_1G	Please rate your ability, over the past 4 weeks, to insert your study gel exactly as you were instructed	If clarification is needed say "This question is asking about the past 4 weeks, or in other words, the past 28 day," If further clarification is needed, say "In the past 4 weeks, how well were you able to insert your study gel exactly as you were told by study staff?"
	One Week Calendar	

Question #	Question	QXQ Instructions
25aT	X day, did you take a lighter tablet?	If clarification is needed say "we are asking about the past 7 days, not including today. Please try to remember whether or not you took your lighter tablet on each day over the past 7 days. We are most interested in knowing on how many of the days in the past seven days not including today you did or did not take your lighter tablet, so if you cannot remember on which day(s) exactly you took your lighter tablet, please guess."
		This is a calendar question. If the participant has difficulty responding to a calendar question, read specific instruction regarding calendar question on page 21.
25bT	X day, did you take a darker tablet?	If clarification is needed say "we are asking about the past 7 days, not including today. Please try to remember whether or not you took your darker tablet on each day over the past 7 days. We are most interested in knowing on how many of the days in the past seven days not including today you did or did not take your darker tablet, so if you cannot remember on which day(s) exactly you took your darker tablet, please guess."
		This is a calendar question. If participant has difficulties responding to a calendar question, read specific instruction regarding calendar question on page 21.
25aG	X day did you insert your study gel?	If clarification is needed say "we are asking about the past 7 days, not including today. Please try to remember whether or not you inserted your study gel on each day over the past 7 days. We are most interested in knowing on how many of the days in the past seven days not including today you did or did not insert your study gel, so if you cannot remember on which day(s) exactly you inserted your study gel, please guess."
		This is a calendar question. If the participant has difficulty responding to a calendar question, read specific instruction regarding calendar question on page 21.
26T	Does taking the study tablets interfere with any of your regular daily activities?	If clarification is needed say "does taking your study tablets disrupt or interfere with your daily work or household duties or any other things that you do on a regular basis?"
26G	Does inserting the study gel interfere with any of your regular daily activities?	If clarification is needed say "does inserting your study gel disrupt or interfere with your daily work or household duties or any other things that you do on a regular basis?"
27T	How difficult is it for you to take your study tablets every day?	If clarification is needed say "please tell us how difficult it is for you to take both of your study tablets once a day as you were instructed"

Question #	Question	QXQ Instructions
27G	How difficult is it for you to insert your study gel every day?	If clarification is needed say "please tell us how difficult it is for you to insert your study gel once a day as you were instructed"
28T	If the tablets you are taking were found to protect women from getting HIV, would you take the tablets daily over a period of many months	If clarification is needed say "thinking into the future, if we find out that the tablets you have been taking can help women from getting HIV, would you take the tablets once a day for a long period of time?"
28G	If the gel you are inserting was found to protect women from getting HIV, would you insert the gel daily over a period of many months	If clarification is needed say "thinking into the future, if we find out that the gel you have been using can help women from getting HIV, would you insert the gel once a day for a long period of time?"
	Partner Involvement	
29T	In the past 3 months, has your primary sex partner become angry about you taking tablets?	If clarification is needed about the time frame, say "by 'in the past 3 months' we mean, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]). If clarification needed, by "angry" I mean that your partner has been upset, yelled or screamed at you because you are taking your study tablets. This includes being violent / physically violent
29G	In the past 3 months, has your primary sex partner become angry about you inserting gel	If clarification is needed about the time frame, say "by 'in the past 3 months' we mean, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]). If clarification needed, by "angry" I mean that your partner has been upset, yelled or screamed at you because you are using your study gel

Question #	Question	QXQ Instructions
30T	In the past 3 months, has your primary sex partner asked you to stop taking tablets?	If clarification is needed about the time frame, say "by 'in the past 3 months' we mean, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]). If further clarification is needed say "in the past 3 months has your primary sex partner, asked you not to take your study tablets, for any reason"
30G	In the past 3 months has your primary sex partner asked you to stop inserting gel?	If clarification is needed about the time frame, say "by 'in the past 3 months' we mean, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]). If further clarification is needed say "in the past 3 months has your primary sex partner, asked you not to insert study gel, for any reason"
31T	In the past 3 months, has your primary sex partner reminded you to take your tablets?	If clarification is needed about the time frame, say "by 'in the past 3 months' we mean, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]). If further clarification is needed say "in the past three months, has your primary sex partner ever done anything to help you remember to take your tablets?"
31G	In the past 3 months, has your primary sex partner reminded you to insert your gel	If clarification is needed about the time frame, say "by 'in the past 3 months' we mean, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]). If further clarification is needed say "in the past three months, has your primary sex partner ever done anything to help you remember to insert your gel?"
32T	In the past 3 months, has your primary sex partner helped you in another way to take your tablets?	If clarification is needed about the time frame, say "by 'in the past 3 months' we mean, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]). If further clarification is needed say "in the past three months, has your primary sex partner ever done anything else to help you or make it easier for you to take your study tablets?"

Question #	Question	QXQ Instructions
32G	In the past 3 months, has your primary sex partner helped you in another way to insert your gel	If clarification is needed about the time frame, say "by 'in the past 3 months' we mean, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]). If further clarification is needed say "in the past three months, has your primary sex partner ever done anything else to help you or make it easier for you to insert your gel?"
33T	How do you think that taking your study tablets affects the sexual pleasure of your primary sex partner?	If clarification is needed say " do YOU think that taking your tablets has an effect on your partner's sexual pleasure in any of the ways listed?"
33G	How do you think that inserting your gel affects the sexual pleasure of your primary sex partner?	If clarification is needed say " do YOU think that using your gel has an effect on your parter's sexual pleasure in any of the ways listed?"
34T	How does taking the tablets affect your sexual pleasure?	If clarification is needed say "does taking your tablets has an effect on your sexual pleasure in any of the ways listed?"
34G	How does inserting the gel affect your sexual pleasure?	If clarification is needed say " does using your gel have an effect on your sexual pleasure in of the ways listed?"
	Product Sharing	
35T	In the past 3 months, how much of your tablets did you give away, exchange, trade or sell?	If clarification is needed about the time frame, say "by 'in the past 3 months' we mean, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]).
35G	In the past 3 months, how much of your gel did you give away, exchange, trade or sell?	If clarification is needed about the time frame, say "by 'in the past 3 months' we mean, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]).

Question #	Question	QXQ Instructions
36T	Now I will ask you who you gave, exchanged, traded or sold your tablets to.	If clarification is needed say "the questions that follow are asking about who you gave, exchanged, traded or sold your tablets to in the past 3 months."
36Ta	your primary sex partner?	If clarification is needed say "In the past three months did you give, exchange, trade, or sell your tablets to your primary sex partner?"
36dT	Family member(s) or relative(s)	If clarification is needed say "In the past three months did you give, exchange, trade, or sell your tablets to family members or relatives?"
36gT	Other study participant(s)	If clarification is needed say "In the past three months did you give, exchange, trade, or sell your tablets to other study participants?"
36iT	Anyone else I have not asked about?	If clarification is needed say "In the past three months did you give, exchange, trade, or sell your tablets to anyone else I have not asked about?"
36G	Now I will ask you who you gave, exchanged, traded or sold your gel to.	If clarification is needed say "the questions that follow are asking about who you gave, exchanged, traded or sold your gel to in the past 3 months."
36aG	your primary sex partner?	If clarification is needed say "In the past three months did you give, exchange, trade, or sell your gel to your primary sex partner?"
36dG	Family member(s) or relative(s)	If clarification is needed say "In the past three months did you give, exchange, trade, or sell your gel to family members or relatives?"
36gG	Other study participant(s)	If clarification is needed say "In the past three months did you give, exchange, trade, or sell your gel to other study participants?"
36iG	Anyone else I have not asked about?	If clarification is needed say "In the past three months did you give, exchange, trade, or sell your gel to anyone else i have not asked about?"

| Question #	Question	QXQ Instructions
37T	In the past 3 months, how many of your tablets were taken from you?	If clarification is needed about the time frame, say "by 'in the past 3 months' we mean, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]). If further clarification is needed, say " by taken from you I mean that someone took your tablets without your permission"
37G	In the past 3 months, how much of your gel was taken from you?	If clarification is needed about the time frame, say "by 'in the past 3 months' we mean, between (early/mid/late [insert month that was three months ago] and now, early/mid/late [insert current month]). If further clarification is needed, say " by taken from you I mean that someone took your gel without your permission"
38T	Now I will ask you who took your study tablets as far as you know.	If clarification is needed say "the questions that follow are asking about who took your tablets without your permission in the past 3 months."
38aT	Your primary sex partner?	If clarification is needed say "in the past 3 months, did your primary sex partner take your tablets?"
38dT	Family member(s) or relative(s)	If clarification is needed say "in the past 3 months, did family members or relatives take your tablets?"
38gT	Other study participant(s)	If clarification is needed say "in the past 3 months, did other study participants take your tablets?"
38iT	Anyone else I have not asked about?	If clarification is needed say "in the past 3 months, did anyone else I have not asked about take your tablets?"
38G	Now I will ask you who took your study gel as far as you know.	If clarification is needed say "the questions that follow are asking about who took your gel without your permission in the past 3 months."
38aG	your primary sex partner?	If clarification is needed say "in the past 3 months, did your primary sex partner take your gel?"
38dG	Family member(s) or relative(s)	If clarification is needed say "in the past 3 months, did family members or relatives take your gel?"

Question #	Question	QXQ Instructions
38gG	Other study participant(s)	If clarification is needed say "in the past 3 months, did other study participants take your gel?"
38iG	Anyone else I have not asked about?	If clarification is needed say "in the past 3 months, did anyone else I have not asked about take your gel?"

Transferring Data from Touch Screen Computers to Designated ACASI Data Manager Computer

At the end of each workday on which at least one ACASI interview is administered, the ACASI Computer data manager will transfer data from the touch screen computers to the ACASI Data Manager laptop computer. The Data Manager laptop is the only one provided to the site that does NOT twist open, as the touch screen laptops do.

1. Remove the 2GB Secure Digital storage device (SD card) from each touch-screen laptop computer. *Please note: The SD cards match the touch screen laptops, so they must always go back into the same one.*

2. If the ACASI Data Manager computer is not already turned on, turn it on and enter the secure power-on password.

3. If the ACASI Data Manager computer is turned on and you are logged in, log out by pressing Start > Shut Down and then choosing log off *username.*

4. Log back into the ACASI Data Manager computer as the computer administrator, using your assigned user name and password.

5. Insert the SD card into the SD card slot on the left side(Lenovo units) or right side(HP units) of the laptop.

6. Double click on the **ACASI data manager** icon, which is located on the Windows Desktop. You will see the dialog box shown in Figure 14 with five (5) buttons.
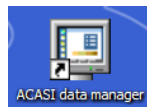
7. Click the first button in the Data Manager Dialog box, which reads "Merge data from SD card to ACASI database." This will copy the new data from the SD card into the ACASI database maintained on the laptop, which is located in the C:\ACASI\DATA folder. After the data are successfully transferred, the transfer program will delete the data from the SD card.

N.B. If you have not inserted the correct SD card, you will see the error message below:

Also note that as you remove the SD card from the touch screen laptop, you might inadvertently move the gray tab on the left side of the card to the "locked" position. Before inserting the SD card into the Data Manager laptop, you must be sure that the card is unlocked by moving the gray tab back up to the unlocked position. If you have locked the SD card before inserting it into the Data Manager laptop, you will see this error message.

This is the correct, "unlocked" position.

If tab is in locked position, push it up to the unlocked position.
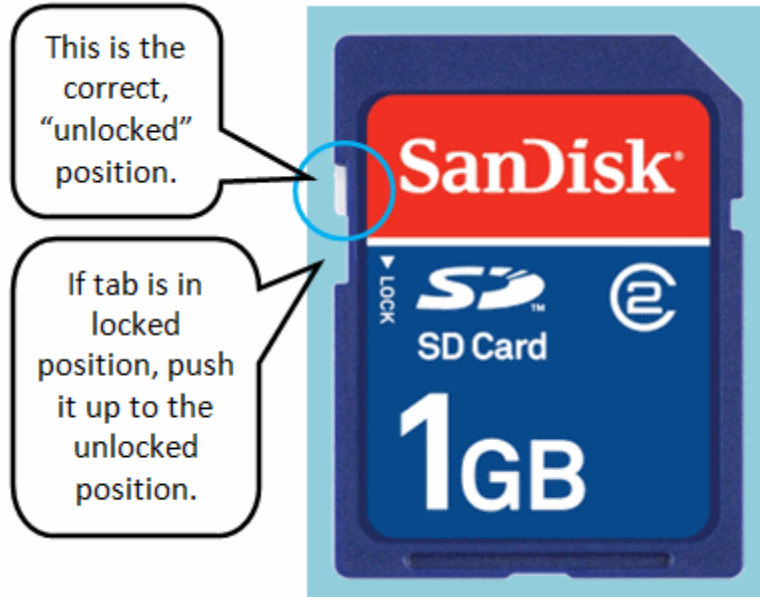
8. After the data are successfully transferred, the transfer program will delete the data from the SD card.

9. If the data are not successfully transferred, please note the error and **email a description of the problem to MTN003acasisupport@mtnstopshiv.org**

10. Remove the SD card from the data manager laptop and insert it in the touch-screen computer immediately to make sure they are kept together.

After completing the data transfer from all the touch-screen computers that completed ACASI questionnaires to the data manager computer, then proceed to backing up the data to your assigned USB key, and then to uploading the ACASI database.

Backing Up the ACASI Database

At the end of each workday on which at least one ACASI interview is administered, after transferring data from touch screen ACASI computers to the designated ACASI laptop and uploading the ACASI database to the MTN SDMC (i.e. SCHARP) via the ATLAS portal, the ACASI Computer data manager will back up the ACASI database and Windows Event Logs to the assigned portable data storage device (USB key).

1. If the ACASI laptop is not already turned on, turn it on and enter the secure power-on password.

2. If logged in, log out of the laptop by pressing Start > Shut Down and then choosing log off *username.*

3. Log back into the laptop as an administrator, using your assigned user name and password.

4. Insert the assigned USB key into one of the USB ports on the left side of the laptop.

5. Double click on the **ACASI data manager** icon located on the Windows Desktop. You will see the dialog box shown in Figure 15 with five (5) buttons.
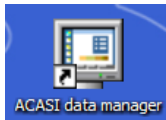
6. Click the third button in the Data Manager dialog box, which reads "Backup ACASI database to USB key."

7. A pop-up window will confirm that the backup has been successfully completed and a window will open up which displays the files that have just been backed up.

8. Remove the memory key by **right** clicking on this icon on the task bar and then left clicking on **Safely Remove Hardware. Click USB Mass Storage Device**, and then click **Stop**. Click **USB Mass Storage Device** again, and then click **OK**, and then **Close**. You will see a message pop up on the task bar, telling you that it is safe to remove the hardware.

9. The USB backup key should be stored securely and in a dry location, in a locked **cabinet.**

Figure 15

Technical Notes on Data Backups

The source ACASI data folder is C:\ACASI\DATA. This is the location in which the ACASI Access database resides.

The ACASI backup program utilizes the compression utility WinZIP to ensure optimum drive space utilization. A backup is performed on the following databases and files:

1. The ACASI database – ACASI_VOICE_DATA.mdb
2. Windows computer System Event Log
3. Windows computer Application Event Log
4. Windows computer Security Event Log
5. System.mdw
6. RespondentResponses.xml

The backup program creates unique backup files of each database each time a backup is run. This is done to prevent overwriting backup files. Each backup file will be date and time stamped within the backup filename. Additionally, a unique backup name is created for each laptop computer.

                        {NAME}   {DATE}   {TIME} {COMPUTER NAME)
Example Backup Filename: acasi_voice-10062007-19311500-acasi-mtn-v-lt1.ZIP
Example Backup Filename: AppEvent-10062007-19311500-acasi-mtn-v-lt1.ZIP
Example Backup Filename: SecEvent-10062007-19311500-acasi-mtn-v-lt1.ZIP
Example Backup Filename: SysEvent-10062007-19311500-acasi-mtn-v-lt1.ZIP
Example Backup Filename: ACASI_xml-10062007-19311500-acasi-mtn-v-lt1.ZIP

The backup filename will indicate the database file that was backed up, followed by the date, time, and assigned ACASI computer name.

Each backup file is compressed and encrypted with the assigned password "ptw472".

When a merge from the SD card is done, the compressed files are stored in date-stamped folders in the C:\acasi\backup directory on the hard drive. The purpose of the USB key is to add an extra level of safety in case the hard drive crashes.

If the automated backup to the USB key does not function properly, please follow the steps below to perform a manual backup. You can simply copy the backup files just like you would with any other file.

   1 – Open Windows Explorer or My Computer.

   2 – Navigate to the C:\acasi\backup directory.

   3 – Select the current date's folder. For example, the files for April 9, 2008 will be in a folder labeled 04092008.

   4 – Select the folder then copy and paste it to the USB key. The drive letter of the key will most likely be E:

Uploading ACASI Data to the SCHARP Atlas Portal

At the end of each workday on which at least one ACASI interview is administered, after transferring data from the touch screen ACASI computers to the designated data manager computer, the ACASI Computer data manager will upload the ACASI database to the MTN SDMC (i.e. SCHARP) via the ATLAS portal.

1. If the data manager program is not open, double click on the **ACASI data manager** icon on the Windows Desktop.

2. You will see the Data Manager dialog box shown in Figure 16.

3. Click on the second button in the Data Manager dialog box, which reads "Upload ACASI database to ATLAS at SCHARP."

4. The files to be uploaded will be date stamped with the current date and will be in the following format:

   acasi_voice-DDMMYYYY-HHMMSS-acasi_mtn-v-lt#.ZIP

   Where DDMMYYY is the day month and year;HHMMSS is the time in hours minutes and seconds, and # is the laptop number. For example:

   acasi_voice-10062007-19311500-acasi_mtn-v-lt1.ZIP

5. With the computer connected to the Internet, do the following:

   a. Go to http://atlas.scharp.org and click on the button for MTN on the front page, then click on **003 (VOICE)** in the left hand navigation menu. You will be asked to sign in at this point. Alternatively, you can browse directly to https://atlas.scharp.org/cpas/Project/MTN/003/begin.view and sign in with your Atlas email and password. It may be helpful to bookmark this page in your web browser so you can return to it easily.

   b. Click the word ACASI on the navigation menu, and then click on the appropriate site.
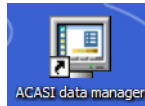
Figure 16

c. Click the 'Upload Files' icon on the lower portion of the page.
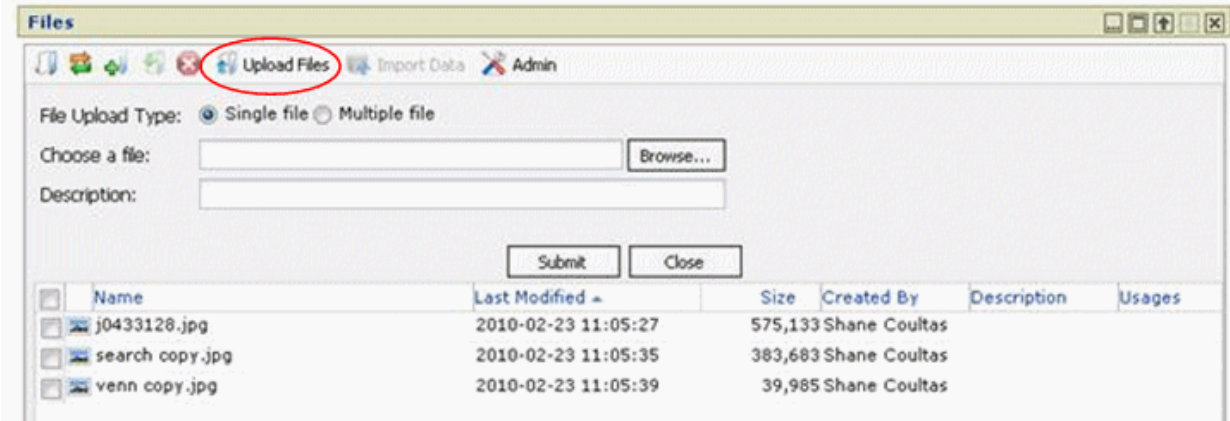
d. Browse to the file to be uploaded on the data manager computer.

e. Click the 'Submit' button.

f. You should now see the file in the upload area. You may refer to this page to view a chronological list of recent uploads and confirm file uploads.
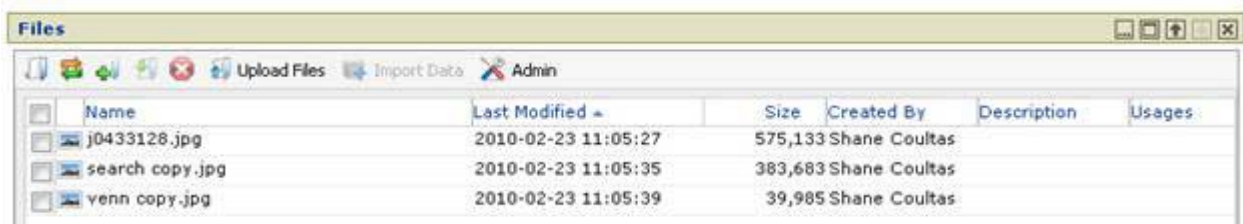
You can sort on any column, much like in Excel or Atlas databases, by clicking the column header or the arrow to its right:
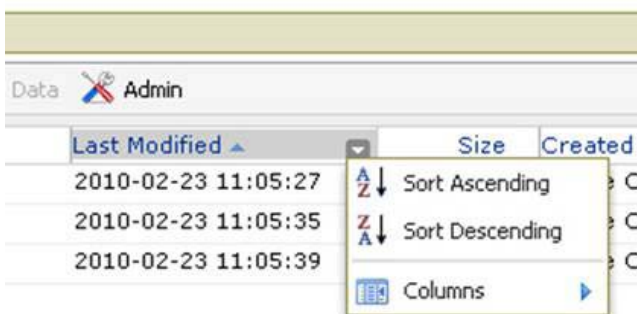
Please Note: The file name must be unique for each upload and the maximum upload size is 250MB.

For any support needs related to the data upload process, please send an e-mail to MTN003ACASISupport@mtnstophshiv.org.

For any technical issues and for questions or problems related to Atlas web sign in, please e-mail atlas@scharp.org.
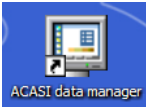
Refresh: This will refresh the contents of the 'Files' module. This is similar to hitting 'refresh' on your browser.
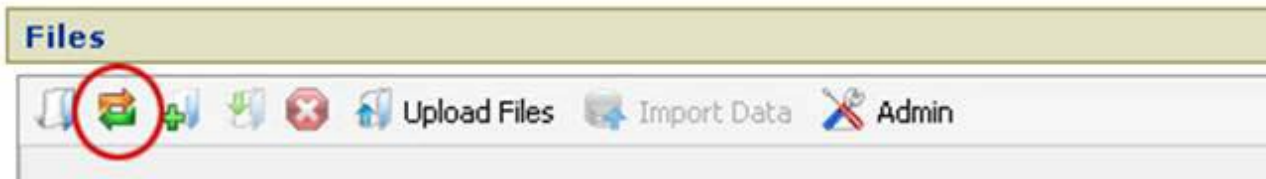
Correcting Key Data in the ACASI Database

The following data are considered "key data" in the ACASI database: PTID, visit code and visit date. If the MTN SDMC (i.e. SCHARP) identifies that any changes to these key data may be needed, the steps below will be followed:

1. The MTN SDMC will contact both the site and ACASI technical staff at the Population Council (namely Paulino Ruiz (pruiz@popcouncil.org) Stan Mierzwa (smierzwa@popcouncil.org) and Samir Souidi (ssouidi@popcouncil.org).

2. Authorized staff at the site will log onto the ACASI laptop as an administrator, using their assigned user name and password, and then complete the following:

3. Double click on the **ACASI Data Manager** icon located on the Windows Desktop.

4. You will then see a Data Manager dialog box with five (5) buttons on it (Figure 17).

5. Click the fourth button in the Data Manager dialog box which reads "Correct Participant ID, Visit Code and Date."

6. Enter your assigned User name and password.

7. Enter the Participant ID number and then click the Search button. The format for the PTID is XXX-XXXXX-X.
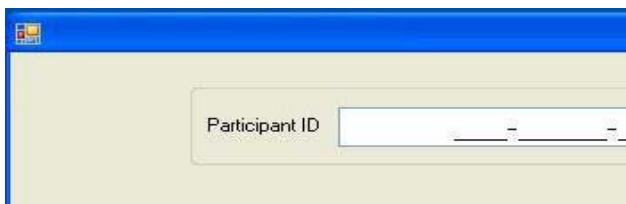
If you do not use the correct PTID format, you will see this message:


Figure 17

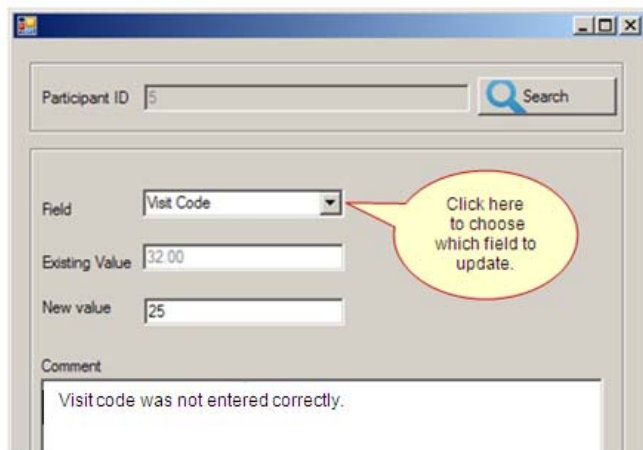If you enter a PTID that is not in the database, you will see this message:

8. After the PTID is correctly entered, you will be presented with a list of questionnaires that have been done for the entered PTID. Based on the information provided to you from SCHARP (PTID, Visit Code, Visit Date, etc.), you will need to select the correct record from the list provided to you. The ID field is a unique internal ACASI identifier which is created because multiple ACASI questionnaires can be done for each PTID. Click "**Select" on the record you wish to update**, even if there is only one match for that PTID.
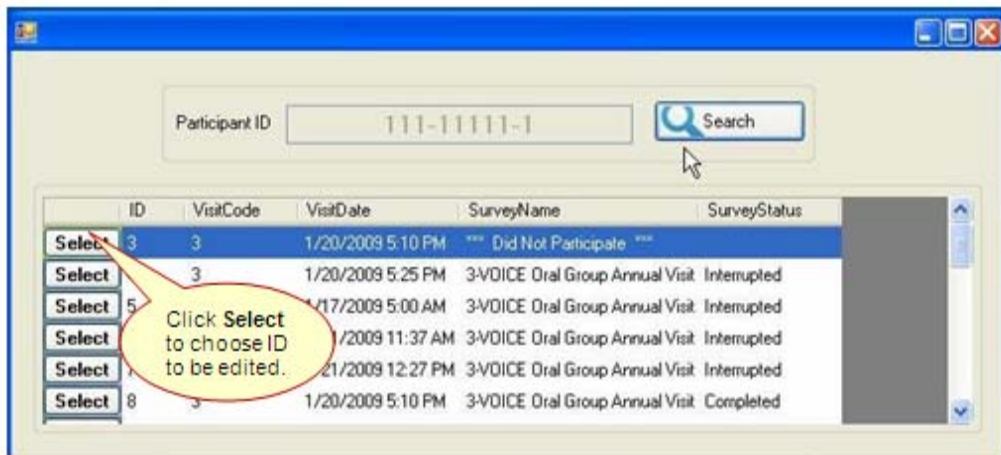
9. Once you choose a record by clicking **Select**, you will see the confirmation dialog box below -

10. Click the drop-down arrow to the right of the Field list to choose which field you need to correct (Participant ID, Visit Code or Visit Date).


11. Press the Tab key on the computer keyboard to display the existing value.

12. Enter the new (correct) value and explain why the change is being made in the comment area.

   If you do not enter a comment, you will see this error message -

13. If you choose to correct the Visit Date, you will see the current date appear as the default. You will need to click on the drop-down arrow to the right of that date to view a calendar and then click on the date you want, *even if the default date is correct.* A value must appear in the "New Value" field in order to be saved by the system.
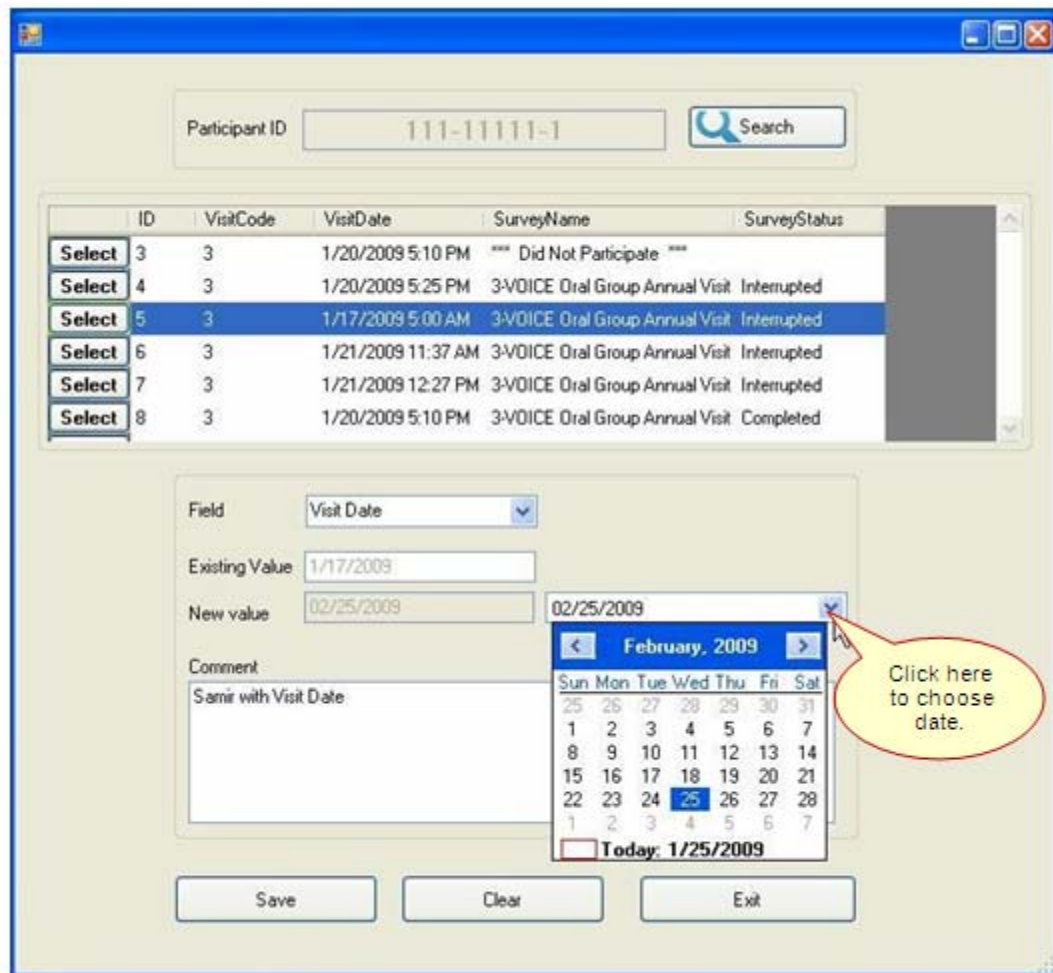

14. Click the Save button if your entry is correct or the Clear button if you need to correct it.

15. After saving the correct value, click the Exit button.

16. In order to upload the latest Data Manager data, with recent changes made to key fields, you will need to go through the Upload process. Please follow the steps to Upload the data to SCHARP as outlined in step 3 of the ACASI Data Manager Cheat Sheet.   When you upload, you will select the latest .zip file from the C:\ACASI\BACKUp and current dates folder.

17. A simple spreadsheet, outlining the change made, who made it, when it was made, and from what value to what value would be reported into the spreadsheet to create a simple tracking.

18. The spreadsheet should be saved, printed and filed at the site.

19. The spreadsheet should be emailed to: MTN003ACASISupport@mtnstophshiv.org

ACASI Data Manager Cheat Sheet

1. Transfer and merge all SD Card data to ACASI database.

A. Start laptop and log in as bond007.

B. On the desktop, double click to start the ACASI Data Manager

C. For each Touch-screen computer:

    i. Remove the SD Card from the side of the computer. Press the SD Card down *lightly* and it should pop out.

    ii. Insert the SD Card into laptop: the card reader is located on the left side of the laptop.

    iii. Count from one to ten.

    iv. Click the "Merge data…" button
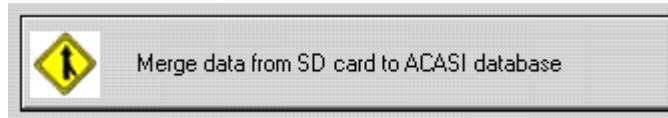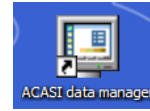
2. Backup the ACASI database, xml, and event log zip files to the USB key.

A. Insert USB Key into laptop. USB slot is located at the back of the laptop (or on the side).

B. Click the "Backup ACASI database to USB key" button.

C. Windows Explorer will open to the USB key backup folder.

D. Verify the file backups.
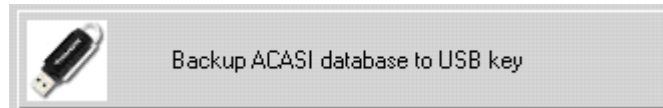
3. Upload ACASI-VOICE backup zip file to atlas.scharp.org.

Once all the data from the SD Cards have been successfully merged to the ACASI database:

A. Click the upload button on the ACASI Data Manager dialog box.

B. Internet Explorer will open at the atlas.scharp.org upload website. Sign in to atlas.scharp.org using your email address and Atlas password.

C. Click the 003 folder and [insert site] folder.

D. Click the "Upload file" link. You will be prompted to browse for the ACASI_VOICE_DB_XXXXXX.zip file.

E. Click the submit button to upload the zip file to atlas.

F. Verify the file backups.
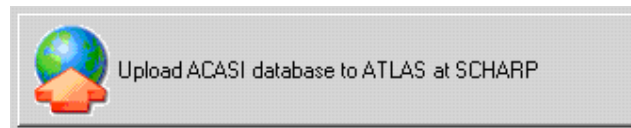
Restoring On-Site ACASI Data

Should a situation arise in which ACASI data needs to be restored to the designated on-site ACASI laptop computer, please email (MTN003acasisupport@mtnstopshiv.org) to request written instructions to complete this process.

Appendix A

Administrator Guidelines for Setting up Participants for ACASI Interview

- Welcome the participant and make her feel as comfortable as possible

- Introduce yourself to participant

- Explain ACASI study procedure

- Stress that we are using ACASI to give as much privacy as possible

- Emphasize that responses are kept confidential

- Only one participant should be in interview room during ACASI interview

- <u>You should leave the room</u> once the participant has completed the practice questions and begins the MTN VOICE ACASI interview. You should however, wait outside the interview room so that you are available should the participants have any questions or problems.

- If participant has questions, you should show participant how to answer question using hypothetical answers, e.g. if you have 3 sex partners you would click on picture 3 times

- To answer questions related to how to use ACASI, please refer to the guide for administrators on how to use ACASI (pages 20-21)

- To answer specific questions on the meaning of the survey questions, please refer to the QxQ Guide (pages 22-34)

- Do not use your cellular phone while setting up the participant for ACASI or when answering questions.

Appendix B

List of Test PTIDs for use when entering Test Data into the VOICE ACASI Questionnaires

Since all data (test and real data) is saved in the Access database, it is critical that when entering test data, you use one of the Test PTIDs listed below. This will ensure that SCHARP will be able to distinguish between test data and "real" data present in the Access database.

Test PTIDs:

999-00062-2
999-00063-5
999-00064-8
999-00065-0
999-00066-3
999-00067-4
999-00068-9
999-00069-7
999-00070-1
999-00071-6

Appendix C

Hardware and Software Recording Requirements

The following items are required to perform the required recordings for the ACASI – VOICE study:

1. **Personal computer with following hardware qualities**
   a. **Sound capability, either via integrated audiosoundcard or integrated audio**
   b. **One Microphone Port In (Audio In)**
   c. **One Headphone Port Line Out (Audio Out)**
   d. **At least 100 MB of free hard disk space (for audio file storage)**
2. **Windows based operating system, either Windows 2000 or Windows XP**
3. **Audacity program or Windows-based Sound Recorder utility (generally installed by default with Windows operating system)**
4. **PC-Based headset with microphone with following qualities**
   a. **In-line and microphone volume control**
   b. **Headphone frequency range of 20 Hz to 20 KHz**
   c. **Microphone frequency range of 100 Hz to 10 KHz**
   d. **Soft foam ear pads**
   e. **One recommended model is the Altec Lansing AHS322 headset**
   f. **Make sure that the microphone and headphone plugs match the pictures or icons on the laptop jacks.**

   When you plug in the headphones, you may see an "Audio System Event" dialog box (at right) asking you for a "supported function". Make sure that Microphone **is selected and then click the OK button.**
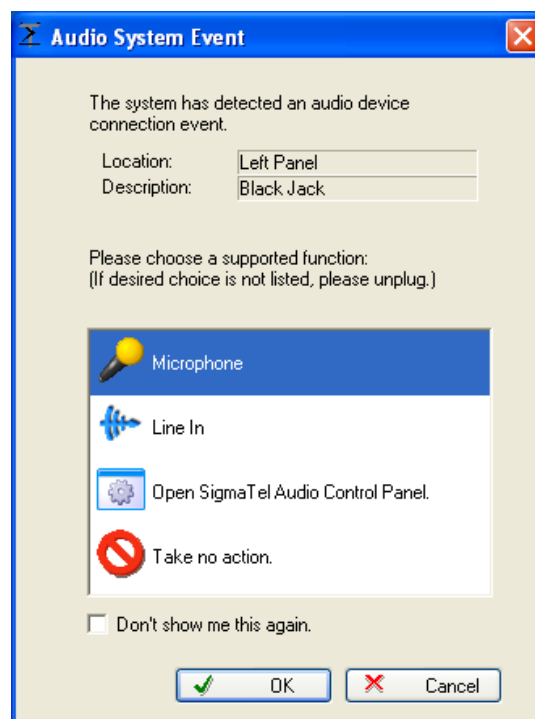
Recording Environment

In order to ensure the best recordings as possible, please do the following:

1. **Select a quiet location. It is recommended that recording be performed in a private room, or an area that is walled off from others.**
2. **Ensure the equipment is set up; this includes the headphone in the proper position.**
3. **Read the audio script in a calm but assertive voice.**
4. **Note that over time you may get tired, so it would be good to take breaks to ensure an effective creation of the audio files.**

5. **Also, please keep in mind:**

    - **<u>underlined words</u> are emphasized, but not strongly emphasized**
    - **slight pauses follow commas**
    - **longer pauses are specified in brackets, e.g., [3 second delay]**
    - **the recordings should be clear and understandable**
   - **the reading of the questions while recording should be at a moderate pace**

There are two different programs that can be used to create the audio files. We have found that Audacity is more flexible and user friendly. In order to run Audacity, double click on its icon   **on your desktop -**

Using Audacity

When Audacity opens, make sure that the display reads External Mic (for microphone), rather than Internal Mic or Line In; it should be selected by default.
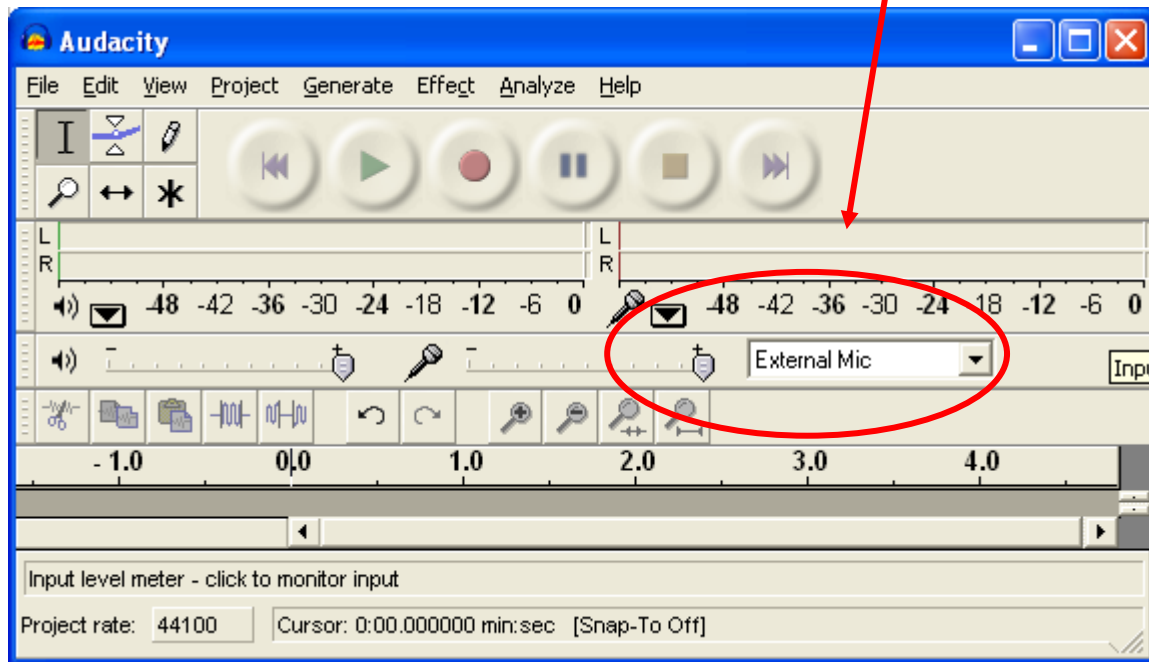
When you are ready to make your first recording, follow the steps below.

Recording the Audio Files

1. **Sit down comfortably at the computer where the recordings will be made.**
2. **Place the headset on your head and position the microphone a few inches away from your mouth.**
3. **Take several deep breaths to relax your voice and remember to speak clearly and assertively.**

4. **Click the red circle button** to start the recording and say "This is a test recording – 1- 2- 3 - "

5. **Click the yellow square button** to stop the recording.

6. **Go to the File menu and choose "Export As Wav" to save your file. Enter ACASITEST as the name of this test file and save it in any convenient location, such as My Documents or the Desktop.**

7. **To play back the recording, press the green arrow/triangle -**

    a. **Play the test recording several times to ensure the quality is good and there is no beginning or ending noise.**

    b. **If the sound quality is not adequate, try adjusting the volume on the headset itself and then play the test audio recording again.**

    c. **If the sound quality is still not adequate, return to the "Create a Test Recording" section above and re-attempt the recording. You can delete the first version of the recording by clicking the black 'X' at the top left corner of the sound "image".**

    Some possible ways to improve quality are:

    - **Adjust the position of the microphone.**

    - **Increase the volume on the microphone.**

    - **Ensure the connections from the headset are secure into the computer.**

    - **Record in a private and or quiet location.**
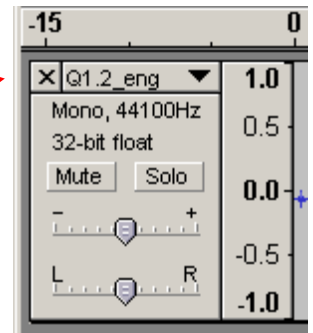
8. **Once you have successfully created a test sound file, you will be ready to record the actual ACASI script. Follow the steps above for creating a test file, but use the naming conventions below. The files should be saved into the** c:\audiofiles **folder. The audio files will ultimately be copied to the handheld computers and kept in a centralized SharePoint project website.**

Naming Conventions for Audio Files

The naming convention of the audio files takes the form of:

    1. question identifier (in bold)

    2. 4-letter language identifier

        eng   (English version)

        chi   (Chichewa version)

    3. the ".wav" extension

Example: For the first introduction (Intro1) and played before the practice question:

filename: intro1_eng.wav (English version)

    intro1_chi.wav (Chichewa version)

Example: For the Administration Questions

filename: a1_eng.wav (English version)

a1_chi.wav (Chichewa version)

Example: For the Main Survey Questions

filename: Q1_eng.wav (English version)

   Q1_chi.wav (Chichewa version)

Using Windows Sound Recorder

1. **Click Start > Programs > Accessories > Entertainment > Sound Recorder. The dialog box below will appear:**

2. **Click the red circle** [icon] **to start the recording and say "This is a test recording – 1 – 2- 3- "**

3. **Click the black rectangle** [icon] **to stop the recording.**

4. **Click File > Save As…, in the File name text box, and enter ACASITEST. Ensure the "Save as" type is set to Sounds (*.wav) and click Save. Remember the specific location where you saved the file.**

5. **Click the black right arrow** [icon] **to play the test recording. Play it several times to ensure the quality is good and there is no beginning or ending noise.**

6. **If the sound quality is not adequate, try to adjust the volume on the headset itself and play the test audio recording again.**

7. **If the sound quality is still not adequate, return to the "Create a Test Recording" section above and re-attempt the recording. Some possible items to adjust to improve quality are:**

   a. **Adjust the position of the microphone**

   b. **Increase the volume on the microphone**

   c. **Ensure the connections from the headset are secure into the computer**

   d. **Record in a private and or quiet location.**

9. **Once you have successfully created a test sound file, you will be ready to record the actual ACASI script. Follow the steps above for creating a test file, but use the naming conventions on pages 3 and 4 for the actual files.**

   The files should be saved into the c:\audiofiles **folder. The audio files will ultimately be copied to the touch-screen computers and kept in a centralized SharePoint project website.**

Appendix D
MTN-003 (VOICE) ACASI Translation Approval Process

Instructions

Each site will be responsible for conducting a thorough review of the local language versions of the behavioral assessments for the MTN-003 (VOICE) trial administered through **Audio Computer-Assisted Self Interview (ACASI)**. Both the audio recording and the written text of the recording will need to be thoroughly reviewed and approved by the site Investigator of Record (or designee).

The purpose of the local language(s) review is to ensure that:
    a) All local language translations accurately reflect the intended meaning of the original ACASI English text
    b) The translated text accurately documents the local language audio recordings
    c) All translations are grammatically correct
    d) All translations will be understandable to VOICE participants
    e) The pace and volume of the audio-recording are appropriate

Each site will conduct the following steps when reviewing the local language versions of the ACASI text and recordings:

1. A minimum of two designated study staff members who speak the local language will review the ACASI Translation Table to make sure that translations reflect the intended meaning of the original English ACASI text, are grammatically correct, and understandable to VOICE participants.
    a. If the translations are accurate, a designated study staff member signs each page of the Translation Table to confirm that the translated text accurately reflects the meaning of the original English ACASI text.
    b. If translation errors are found, designated study staff members will make all necessary changes, highlight changes in the Translation Table, and then a designated staff member signs each page of the Translation Table to confirm that the updated translated text accurately reflects the meaning of the original English ACASI text. The designated staff member who signed the Translation Table will ensure that these changes are also made in the audio recordings.
2. A minimum of two designated study staff members who speak the local language will listen to all local language audio recordings for the VOICE ACASI program to make sure they accurately reflect the reviewed translated text and that the pace and volume of the files are appropriate. If errors are found, the designated staff members will inform Stan Mierzwa (smierzwa@popcouncil.org) from Population Council and ensure that the erroneous files are re-recorded in collaboration with Population Council.
3. Site Investigator of Record (IoR) or designee signs the "Translation Approval form" (**one signed form per local translated language**) to attest that the steps described above have been followed and that the written text and audio recordings have been properly translated.
4. The following documents should be emailed to Ariane van der Straten (ariane@rti.org) from the MTN Behavioral Research Working group (BRWG) and Stan Mierzwa (smierzwa@popcouncil.org) from Population Council:
    a. A scanned copy of the signed Translation Approval Form
    b. A scanned copy of the signed Translation Table pages
    c. The final version of the Translation Table (in Excel file with all changes highlighted)
    Original forms will be filed in the VOICE essential document files.

MTN-003 (VOICE) ACASI Translation Approval Form

Complete and sign the form, scan it and email it with the signed Translation Table pages to Ariane van der Straten (ariane@rti.org) from the MTN Behavioral Research Working group (BRWG) and Stan Mierzwa (smierzwa@popcouncil.org) from Population Council.

Site: _____

Language: _____

I, _____ attest that the _____ site
      NAME, TITLE,   NAME OF SITE

has conducted a thorough review of the above language translations of the written text and audio recording for the VOICE ACASI program using the instructions provided by the MTN Behavioral Research Working Group (BRWG).

I hereby attest that:

a) All _____ (NAME of LANGAGE) translations accurately reflect the intended meaning

    of the original ACASI English text

b) The translated text accurately documents the local languages audio recordings

c) All translations are grammatically correct

d) All translations will be understandable to VOICE participants

e) The pace and volume of the audio-recording are appropriate

Date:

Signature:

Appendix F: ACASI – Cheat Sheet

Set-Up
1. Power on password is **dvd15**
2. Account credentials is
   o Username: **acuser**
   o Password: **color93**
3. Plug headphone into green round port on right-side of laptop
4. Plug USB mouse into USB port on right-side of laptop (USB Mouse to assist ACASI Administrators with administrative section of ACASI. *Note: If stylus causes difficulties, participant can also use mouse to complete ACASI questionnaire*)

Figure 1

Administrator ID's assigned by country:

•	**101-199**	**Uganda**	• **500-599**	**Malawi**
•	**200-299**	**Zimbabwe**	• **600-699**	**Zambia**
•	**300-499**	**South Africa**		

Test PTID (for staff to train and retrain practicing ACASI)
999-00062-2
999-00063-5
999-00064-8
999-00065-0
999-00066-3
999-00067-4
999-00068-9
999-00069-7
999-00070-1

Touch-screen Swivel
After completing the Administrative section of ACASI interview, ACASI Administrators should swivel the screen of the laptop so the participant does not use keyboard.

Exiting the ACASI Program

At any time, you may terminate the interview application by double clicking w/mouse (or double tapping) on the top left

corner of the screen where you see the small white square with a black border ☐ . A gray box will pop up, asking if you would like to exit the survey. During the administrative setup, you may double tap on the MTN logo to exit the program. Please note, each time an interview is completed, the computer will automatically reboot and take you back to the initial login screen.

ACASI Step by Step

1. Introduce yourself, welcome the participant and make her feel as comfortable as possible

2. Explain ACASI procedure
   - Stress that we are using ACASI to give as much privacy as possible
   - Emphasize that responses are kept confidential
   - Tell participant what to expect during the ACASI interview

3. Enter information in **Administrative Section**

Type Administrator ID	
Select the Questionnaire	
Type Participant ID number (PTID)	Confirm by entering it again
Visit code	Select from **drop-down menu** *(no consistency check with questionnaire)*
Visit date	Confirm by selecting day, month, year from **drop-down menu**
Questionnaire language	Select one of nine languages
Participant's # of live births	Select from **drop-down menu** per her self-report at ACASI set up
Participant's age	Select from **drop-down menu** per her self-report at ACASI set up
# of days she went to the market in past 7 days	From **drop-down menu** per her self-report at ACASI set up

4. Swivel the screen of the laptop towards the participant
5. Demonstrate use of touch-screen computer, headphones, stylus
6. Administer **Practice Questions**: 5 questions completed by participant with guidance of ACASI administrator
   - Explain different ways to answer questions:
     - COLORED SQUARES
     - PICTURES
     - NUMBERED BOXES
     - SUBTRACTING
     - ZERO
   - Explain how to check that her answer was "recorded" (blue highlight for categorical responses; correct number in box for count responses)
   - Explain how to answer count questions and calendar questions
   - Explain how to repeat a question
   - Explain how to move to the next question
   - Explain how to return to a previous question (can only go back ONE question to change answer)
   - Explain how to skip a question (only to be used if she refuses to answer)
   - Explain how to change a response (e.g. from "yes" to "no")
   - Repeat Practice Questions again if participant is struggling with use of computer
7. **Administer ACASI Questionnaire/Survey**: to be completed by Participant
   - Ask if participant has any questions before proceeding.
   - Tell her you will leave the room to give her privacy.
   - Tell her you will be sitting just outside the room if she has any questions.
   - Remind her to take off the headphones and come get you when she is finished or if she has any questions during the interview.
   - Leave the interview room and wait outside the room.
8. When the ACASI is finished, **thank the participant** for her time and effort in answering the questions.
   - Make sure she returns the stylus or leaves it with the touchscreen computer.
9. For ACASI questions or concerns, please email the following: mtn003acasisupport@mtnstopshiv.org

Appendix F:ACASI Questionnaire Procedures for participants on temporary product hold

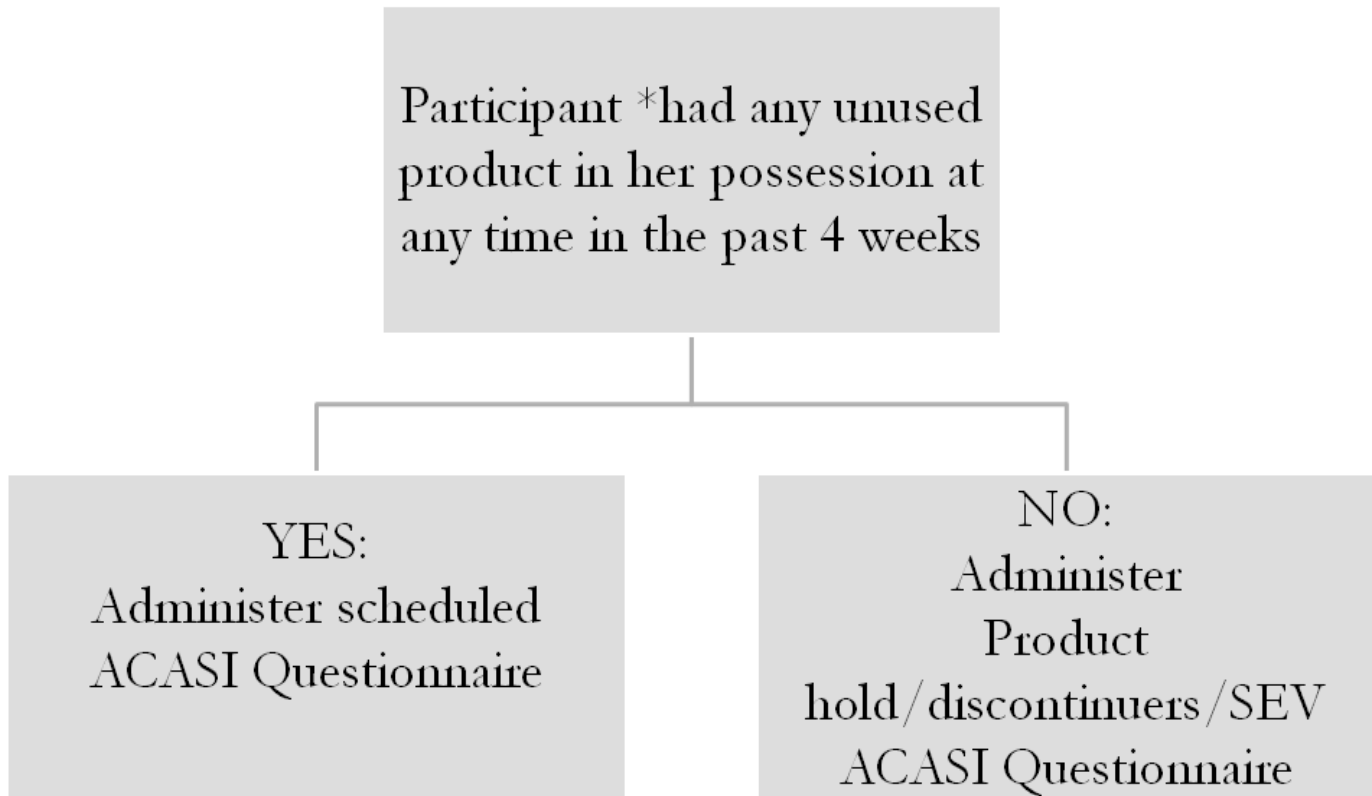**or who have permanently discontinued study product use**

1. The following ACASI Administration rules apply to participants who have **not been exposed to study product in the 4 weeks or more before the current visit date.** This means that no study product has been re-supplied/re-issued to the participant in the 4 weeks or more before the current visit date, **and** that the participant did not have any remaining unused product (regardless of expiry) in her possession in the 4 weeks or more before the current visit date. This applies to product holds/discontinuations that are initiated *by site staff*, as well as cases where a participant chooses on her own to stop using study product for any length of time.

   - Site staff should administer the Product Hold/Discontinuers/SEV ACASI questionnaire at the participant's quarterly, semiannual, and annual visits. Site staff should continue to administer this same questionnaire to her at all subsequent quarterly, semiannual, annual, and PUEV visits where she has not been exposed to study product in the 4 weeks or more prior to the visit.

2. If a participant had any unused product in her possession in the 4 weeks prior to the current visit date (regardless of whether or not she is on a site-initiated product hold/discontinuation, and regardless of whether or not she has used the study product), the participant should be administered the regularly scheduled ACASI questionnaire.

   - When she completes the regularly scheduled ACASI questionnaire, she will be asked questions to rate her ability to use study product **as instructed.** The participant should respond based on her experience during the days she was expected to use study product; that is, the days where she did not have a site-initiated product hold or permanent discontinuation, if any. For the calendar questions (e.g., question 25), she should respond "NO" for the days in which she did not use study product. For all other product-related questions (e.g., question 26 and beyond) she should respond based on her experience during the days she was expected to use study product. ***Note**: clinic staff must provide these additional instructions to the participant prior to the start of her ACASI interview.*

3. If a participant is placed on product hold AT a quarterly visit, she should complete the regularly scheduled quarterly (semiannual or annual) ACASI interview as she was expected to use product up to that visit date. If she remains on hold until the next quarterly visit, she would then be administered the Product Hold/Discontinuers/SEV at that next quarterly visit.

Procedures for participants who terminate early from VOICE

4. For participants who terminate from the study prior to their expected product use end date, the PUEV is conducted at the study month when the participant terminates from the study. For example, a participant is expected to remain on study product for the minimum amount of time allowed per protocol (12 months). The participant presents to the site clinic for her Month 5 visit and informs study staff that she no longer wants to participate in the study. If the participant is willing, study staff conduct the PUEV at this time (Month 5) and administer the Annual/PUEV Oral or Vaginal questionnaire, as appropriate.

Rule for visit-specific ACASI administration

Participant *had any unused product in her possession at any time in the past 4 weeks

YES: Administer scheduled ACASI Questionnaire

NO: Administer Product hold/discontinuers/SEV ACASI Questionnaire

   *This includes product that may have expired, product that was supposed to be returned to the site but is still in the participant's possession, and product that the participant may not have been expected to use in the case of a site-initiated product hold/discontinuation.

Appendix G: ACASI Interview Schedule - Oral

Visit	Visit Code	ACASI Questionnaire to administer	Administer to:
Enrollment	3.0	Enrollment	All participants enrolled
Month 3*	6.0	First Quarterly Oral	All participants randomized to oral arm (except participants with no unused product in their possession in the past 4 weeks or more)
Months 6, 9, 15, 18, 21, 27, 30	9.0, 12.0, 18.0, 21.0, 24.0, 30.0, 33.0	Regular Quarterly Oral	All participants randomized to oral arm (except participants with no unused product in their possession in the past 4 weeks or more)
Months 12, 24, and PUEV/Early Termination	15.0, 27.0, visit code associated with study month when PUEV/Early Termination occurs**	Annual/PUEV Oral	All participants randomized to oral arm who are completing an annual visit, scheduled PUEV, or early termination visit (except participants with no unused product in their possession in the past 4 weeks or more)
Study Exit (SEV) or any quarterly or semiannual visit where participant has not been exposed to study product in the past 4 weeks	89.0, visit code associated with study month when quarterly or semiannual visit occurs**	Product Hold/ Discontinuers/SEV	Participants randomized to oral arm who are completing a scheduled SEV, or who have had no unused product in their possession in the past 4 weeks or more.

*If participant misses her Month 3 Visit, administer the First Quarterly Oral ACASI questionnaire at the first quarterly visit she completes.
**Refer to SSP Section Table 14-2 for the list of visit codes assigned to each study visit

Appendix H: ACASI Interview Schedule – Vaginal

Visit	Visit Code	ACASI Questionnaire to administer	Administer to:
Enrollment	3.0	Enrollment	All participants enrolled
Month 3*	6.0	First Quarterly Vaginal	All participants randomized to vaginal arm (except participants with no unused product in their possession in the past 4 weeks or more)
Months 6, 9, 15, 18, 21, 27, 30	9.0, 12.0, 18.0, 21.0, 24.0, 30.0, 33.0	Regular Quarterly Vaginal	All participants randomized to vaginal arm (except participants with no unused product in their possession in the past 4 weeks or more)
Months 12, 24, and PUEV/Early Termination	15.0, 27.0, visit code associated with study month when PUEV/Early Termination occurs**	Annual/PUEV Vaginal	All participants randomized to vaginal arm who are completing an annual visit, scheduled PUEV, or early termination visit (except participants with no unused product in their possession in the past 4 weeks or more)
Study Exit (SEV) or any quarterly or semiannual visit where participant has not been exposed to study product in the past 4 weeks	89.0, visit code associated with study month when quarterly or semiannual visit occurs**	Product Hold/ Discontinuers/SEV	Participants randomized to oral arm who are completing a scheduled SEV, or who have had no unused product in their possession in the past 4 weeks or more.

* If participant misses her Month 3 Visit, administer the First Quarterly Vaginal ACASI questionnaire at the first quarterly visit she completes.
**Refer to SSP Section Table 14-2 for the list of visit codes assigned to each study visit