



MTN-034 ACASI

User Manual

Version 1.0

5 February 2019

TABLE OF CONTENTS

LIST OF TABLES	3
LIST OF FIGURES RELATED TO TABLET SETUP	3
LIST OF SCREEN SHOTS FROM THE ACASI APP	4
1. INTRODUCTION	5
2. EQUIPMENT	6
3. TABLET MAINTENANCE.....	6
4. TABLET SETTINGS	6
Turning on Tablet	6
Entering Start-up PIN.....	7
Adjusting Tablet Settings	7
Font and Brightness	8
Notifications.....	9
5. USER IDS, PASSWORDS AND SECURITY.....	11
6. SETTING UP THE TABLET FOR SURVEYS.....	14
7. ADMINISTRATIVE SETUP	18
8. SETTING UP THE PARTICIPANT.....	27
Using the Tablet	27
Touch screen training.....	27
9. PRACTICE QUESTIONS.....	28
10. EXITING THE ACASI PROGRAM	34
11. REPORTS AVAILABLE ON ACASI TABLETS	35
10. ACASI DATA MANAGEMENT.....	38
Data Manager Computer	38
Exporting Files from the Tablet to the Data Manager Laptop	38
Importing XML Files from Tablet	40
Merging Exported Files on the Data Manager Laptop	44
Uploading ACASI Data to the SCHARP Atlas Portal	45
Backing up the ACASI Data.....	52
12. CORRECTING KEY DATA IN THE ACASI DATABASE.....	54
APPENDIX A: TRAINING SCRIPT FOR STUDY STAFF	60
APPENDIX B: HARDWARE AND SOFTWARE RECORDING REQUIREMENTS	62
APPENDIX C: SOP FOR RECOVERING LOST PIN	66

LIST OF TABLES

Table 1. Roles, User IDs and Passwords.....	10
Table 2. Tablet Administrator and Interviewer IDs and Study Sites.....	11
Table 3. Visit Schedule, Survey Name and Visit Codes for ACASI REACH.....	23

LIST OF FIGURES RELATED TO TABLET SETUP

Figure 1 - Tablet Buttons.....	7
Figure 2 - Enter Startup PIN.....	7
Figure 3 - Tablet Settings and Controls.....	8
Figure 4 - Display and Font Size.....	9
Figure 5 - Brightness and Font Size.....	9
Figure 6 - Notifications.....	10
Figure 7 - Screen Lock Options.....	13
Figure 8 - Set Custom PIN.....	13
Figure 9 - Enter PIN after Customizing.....	13
Figure 10 - Select Report.....	13
Figure 11 - Counseling Report.....	146
Figure 12 - Sample Report.....	37
Figure 13 - No Surveys Match Selected Criteria.....	37
Figure 14 - Data flow from Tablets to Laptop to SCHARP.....	38
Figure 15 - Export Data toXML.....	39
Figure 16 - Confirm Surveys Exported.....	39
Figure 17 - Trust Computer Pop-up Box.....	40
Figure 18 - Import XML Files from the Tablet.....	40
Figure 19 - ACASI Data Manager Icon on Desktop.....	41
Figure 20 - Confirm Surveys Exported.....	41
Figure 21 - No XML File Found.....	42
Figure 22 - Error Connecting to Tablet.....	43
Figure 23 - Merge Exported Files.....	44
Figure 24 - Data Merged Successfully.....	45
Figure 25 - Upload Data to SCHARP.....	46
Figure 26 - Data Prepared Successfully.....	47
Figure 27 - Folder Automatically Created.....	47
Figure 28 - SCHARP Home Page.....	48
Figure 29 - SCHARP Terms of Use.....	48
Figure 30 - Choose MTN034.....	49
Figure 31 - MTN Secure Sections.....	49
Figure 32 - SCHARP Login Screen.....	50
Figure 33 - Upload Data to SCHARP.....	50
Figure 34 - Sort Data.....	50
Figure 35 - Refresh List of Surveys.....	51
Figure 36 - Make a Copy of Database on USB Key.....	52
Figure 37 - Failed to Find USB Key.....	53
Figure 38 - Eject USB Key.....	53
Figure 39 - Correct Key Data.....	54
Figure 40 - User Name and Password to Correct Data.....	55
Figure 41 - Search Window to Correct Data.....	55
Figure 42 - Select Record.....	56
Figure 43 - Update Field.....	57
Figure 44 - Correct Duplicate Entry.....	58
Figure 45 - Correct Visit Date.....	59

LIST OF SCREEN SHOTS FROM THE ACASI APP

Screen 1 - Tablet Admin Login.....	15
Screen 2 - Check for Updates.....	16
Screen 3 - Downloading Updates.....	16
Screen 4 - Check for Audio Updates.....	17
Screen 5 - Audio Updates Downloading.....	17
Screen 6 - Check App download.....	18
Screen 7 - Enter Admin ID.....	18
Screen 8 - Enter New Survey.....	19
Screen 9 - Select Site Name and Interviewer ID.....	19
Screen 10 - Enter and Confirm Respondent ID.....	20
Screen 11 - Select Month of Visit, then select Age.....	20
Screen 12 - Select Month of Visit.....	21
Screen 13 - Select Exact Date.....	21
Screen 14 - Error with Date Mismatch.....	22
Screen 15 - Error No Language Selected.....	22
Screen 16 - Survey Drop-down list.....	22
Screen 17 - Select Visit Code.....	23
Screen 18 - Choose or Skip Practice Questions.....	25
Screen 19 - Ready to Start Survey.....	26
Screen 20 - Resume Incomplete Survey.....	27
Screen 21 - Choose Survey to Resume.....	28
Screen 22 - Skip Question and Pop-up Message.....	29
Screen 23 - PQ1 and Repeat Button.....	30
Screen 24 - PQ2 Number Keypad.....	30
Screen 25- PQ3 Multiple Choice.....	31
Screen 26 - PQ4 Multiple Choice.....	31
Screen 27 - PQ5 Multiple Choice.....	32
Screen 28 - PQ6 - Choose Multiple Responses.....	32
Screen 29 - Repeat Practice Questions.....	32
Screen 30 - Quit Survey Before Finishing.....	34
Screen 31 - Confirm Quit App/Survey.....	32

1. INTRODUCTION

This ACASI User Manual is intended as a reference for staff implementing MTN-034 (REACH) at the following clinical trial sites:

- Emavundleni CRS – Cape Town, South Africa
- KEMRI CRS – Kisumu, Kenya
- MU-JHU, Uganda CRS – Kampala, Uganda
- Spilhaus CRS – Harare, Zimbabwe
- Wits RHI CRS – Johannesburg, South Africa

The purpose of the manual is to provide instructions on how the ACASI App is to be used by study staff at each site, including orienting users to the equipment, settings, security, and roles and responsibilities.

A set of “Figures” accompany instructions illustrating tablet set up. A set of “Screens” accompany instructions and examples for the MTN-034 App. The table of contents lists each figure and screen shot for easy access.

The manual describes how the App functions but does not include a detailed review of all questions. Please refer to the SSP Section 11.2 for an overview of ACASI in the MTN-034 trial.

For any questions about the ACASI system, staff should send an email to the MTN-034 support portal:

MTN034ACASI@mtnstopshiv.org.

ACASI ROLES AND RESONSIBILITIES

There are three roles for the ACASI surveys that are described in detail below:

1. **Data Manager** – Each site has one Data Manager. This person is responsible for overseeing ACASI data collection. S/he is responsible for assigning Administrative IDs to Interviewers, importing the surveys from individual tablets to the Data Manager PC, merging the surveys into one file on the Data Manager PC, and uploading the data from the Data Manager PC to SCHARP.
2. **Tablet Administrator** – Each site will have up to three Tablet Administrators, corresponding to the number of tablets at each site (3). Each Tablet Administrator will be assigned to a specific tablet and will be responsible for starting that tablet each day (when there are surveys), and for performing the maintenance tasks described in Section 3.
3. **Interviewer** – Each site will have multiple Interviewers who are responsible for training the participants to self-administer the ACASI interview. The Interviewers will start each survey, fill in the administrative information in each survey, teach the participants how to use the ACASI system and assist participants if they have questions or problems while they are taking the survey. Interviewers can use any of the available tablets. Interviewers will run the counseling report as soon as each participant completes her survey and will follow the site SOP if a participant requests counseling.

In many instances, the same person will be both a Tablet Administrator and Interviewer.

2. EQUIPMENT

Each participating MTN-034 study site has been provided with the following ACASI equipment:

- 3 Samsung Galaxy Android tablet computers (“Tablets”) and chargers
- 1 designated ACASI laptop computer for Data Manager function and charger (Data Manager PC)
- 1 USB portable data storage device (“USB key”)
- 1 USB cable
- 3 Audio headphones

The above-listed equipment should be used only for purposes of data collection and transfer.

The equipment should not be used for any other office, business or leisure activities. No additional software should be installed on any of the tablets or the Data Manager PC. None of the devices may be used for playing games, browsing the Internet, or any other application. No technical changes should be made to any of the equipment unless directed by Information Technology (IT) personnel at the Population Council.

3. TABLET MAINTENANCE

MAINTENANCE TASKS MUST BE DONE AT LEAST ONCE A WEEK IN WEEKS WHEN NO ACASI SURVEYS ARE DONE.

Each participating study site must specify in its site-specific data management standard operating procedures (SOPs) for MTN-034 where the above-listed equipment will be securely stored and which study staff are authorized to access the equipment.

An MTN-034 staff member designated as responsible for proper storage of the tablets should perform the following maintenance tasks with each tablet on each workday that an ACASI interview is conducted, or once a week in any week that no ACASI surveys are administered:

- Turn on the tablet and enter the PIN.
- Verify that the tablet boots up properly and is functioning.
- Clean the touch screen tablets with cloth. DO NOT use liquid cleanser or water.
- Charge the tablet.

At the end of each workday, study staff designated as responsible for proper storage of the touch screen tablets and the designated Data Manager PC laptop should ensure that they have been properly turned off or shut down and placed in a secure, dry location until the next day of use.

4. TABLET SETTINGS

Turning on Tablet

The power button is located the left side of the tablet if you are looking at the back (see Figure 1).

To turn on the tablet, **press and hold the power button for approximately 5 seconds** until you see the Samsung Galaxy logo appear on the screen.

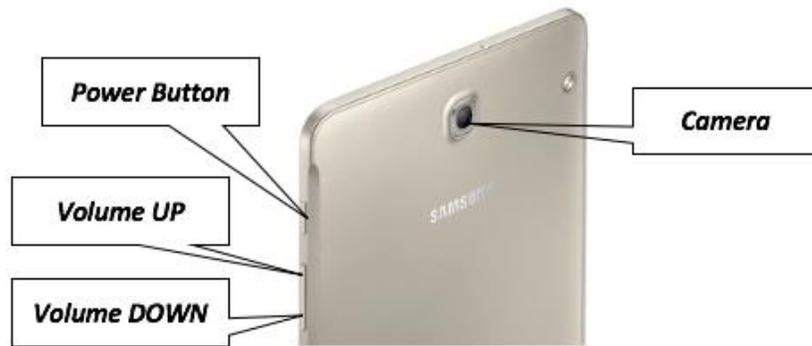


Figure 1 - Tablet Buttons

Entering Start-up PIN

Once the tablet has been powered on, you will be prompted to “swipe” at the bottom of the screen to enter a personal identification number (PIN) to unlock the device (Figure 2a). When you click in the space a box will pop up (Figure 2b) for you to type in your PIN.

The default PIN for all tablets is **dvd15**. When sites are activated, each Tablet Administrator will have a unique 4-digit PIN that will be used to unlock his/her tablet once the study starts (see Section 4 for details on setting up unique PINs).

The unique PIN will only be used once the study starts. The default PIN will be used only for testing and training.

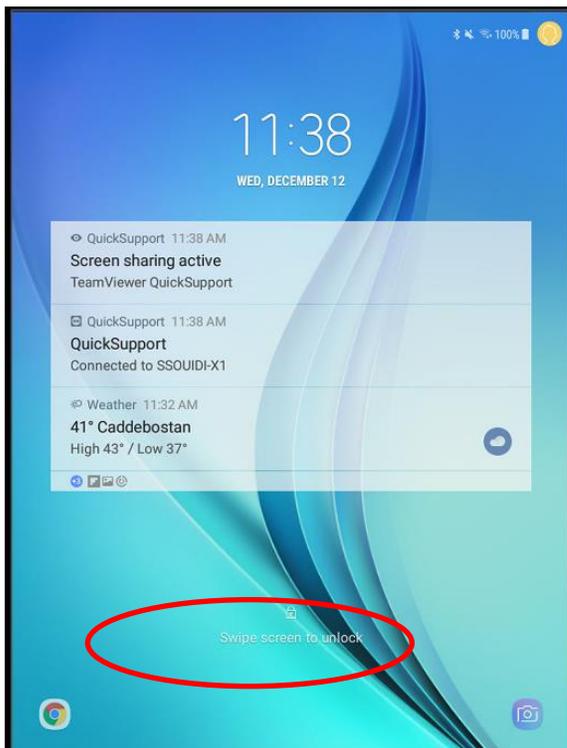


Figure 2a – Swipe Homepage to enter PIN

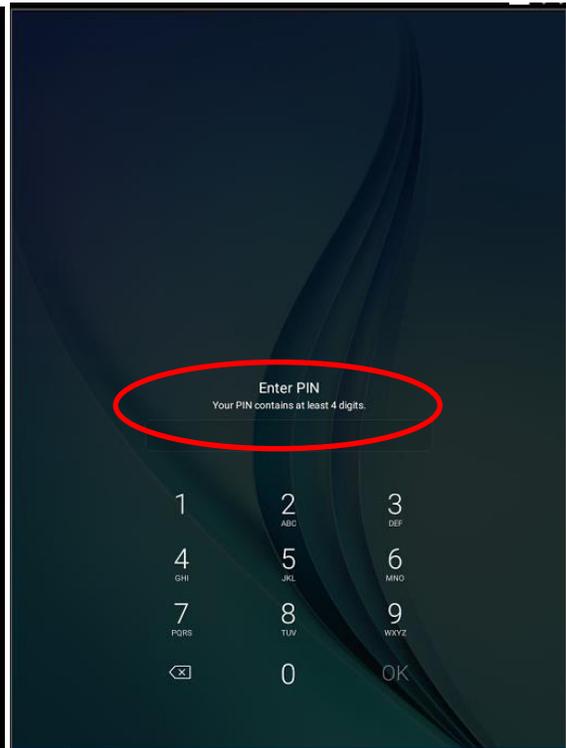


Figure 2b – Enter PIN

Adjusting Tablet Settings

To adjust settings (e.g. Display, Wifi, Notifications) you will need to go to “Settings.” To access the Settings icon, press the date and time on the top of the screen below (left side of Figure 3), which will open the menu on the right containing the Settings icon, circled in red below (right side of Figure 3).



Figure 3 - Tablet Settings and Controls

Font and Brightness

You may want to adjust the font size and/or brightness of the tablet to make it easier to use.

1. From the home screen, press and hold the bar showing date/time at the top of the screen (Figure 3).
2. Touch **Settings** (as in Figure 3).
3. On the left side of the Settings window, touch **Display** (as shown in Figure 4).
4. On the right side of the screen, touch **Screen zoom and font** to increase the size of all of the text. The default is “Small” or “Tiny,” so you will want to make it “Large” (Figure 4, bottom).

Do not change the Font Style, just the size.

5. If **Auto brightness** is turned on, turn it off by sliding the bar to the left (Figure 5). Once you have turned Auto brightness off, you can slide the circle along the bar to increase or decrease brightness.

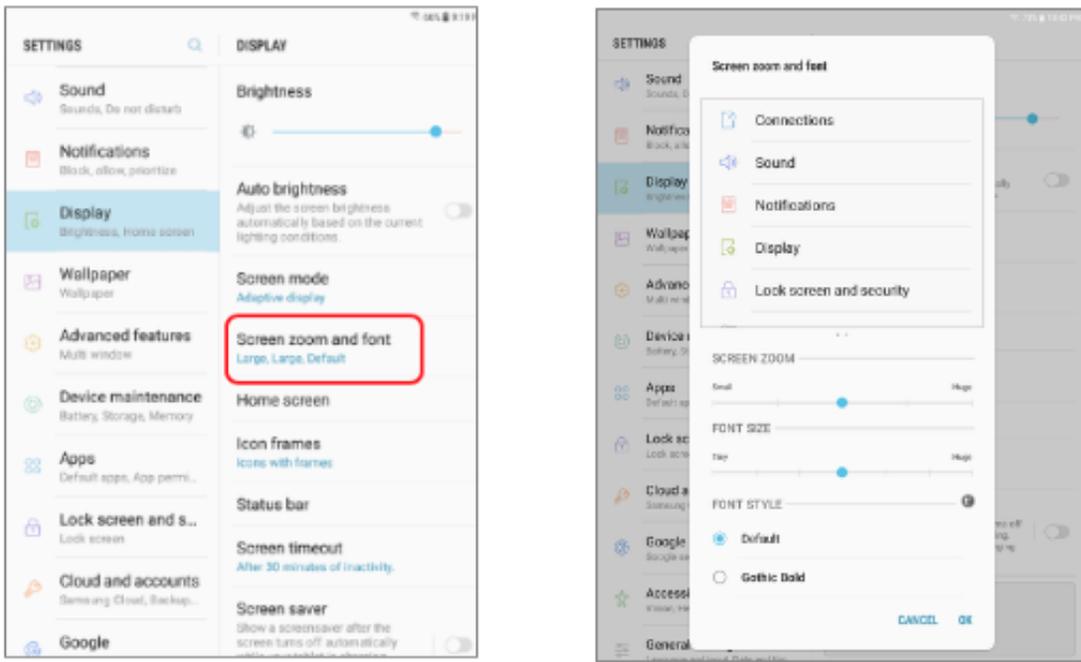


Figure 4 - Display and Font Size

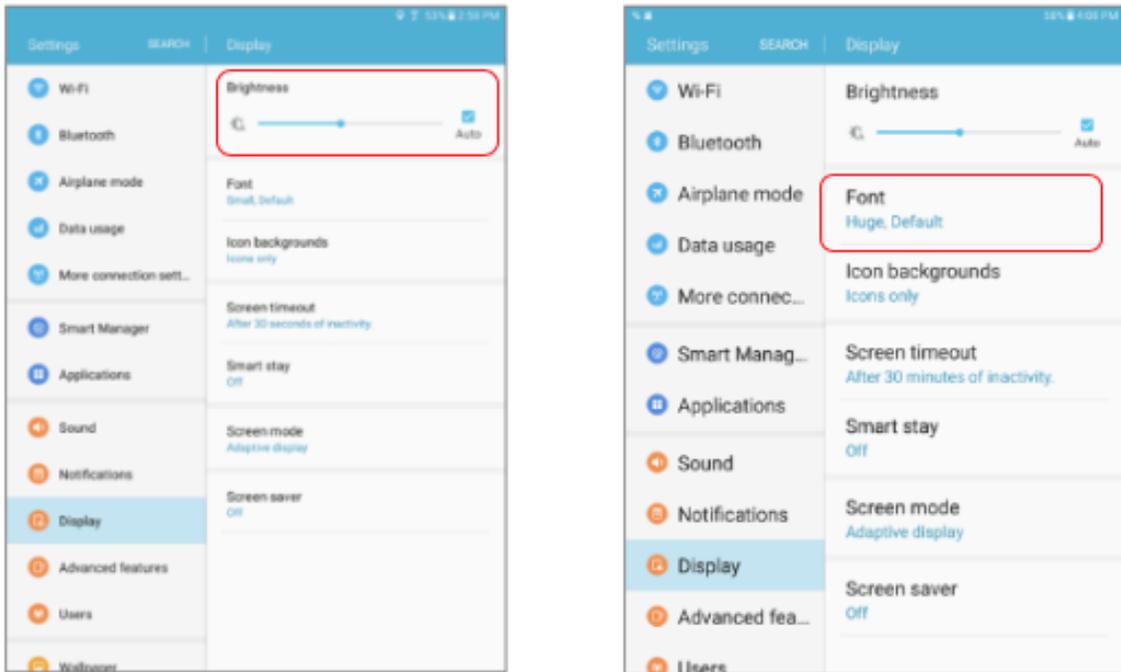


Figure 5 - Brightness and Font Size (Tiny on left image, Huge on right image)

Notifications

After adjusting the Display settings, click Notifications to make sure all notifications are turned OFF, except:

- MTN034 App icon
- Quick Support
- Team Viewer

To turn notifications OFF, slide the button to the left. To turn notifications ON, slide button to the right (Figure 6):

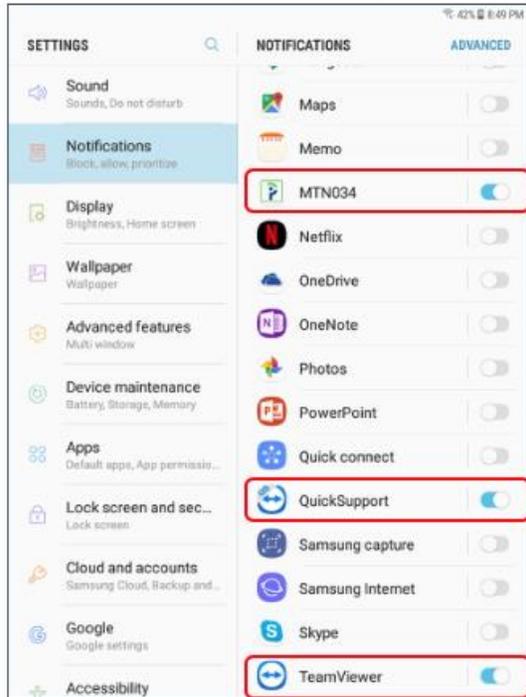


Figure 6 - Notifications

5. USER IDS, PASSWORDS AND SECURITY

This section outlines the relevant user names, IDs and/or passwords for the various ACASI roles, summarized in Table 1 and explained in detail below.

Table 1. Roles, User IDs and Passwords

Tool or system that log-in applies to:	Role (number of staff fulfilling this role per site)	Purpose	User ID/Name Assigned by	Password Assigned by	PIN Assigned by
Data manager laptop	Data Manager	Device security: Unlock laptop	Population Council	NA	Population Council
Data manager laptop	Data Manager	Program security: needed to launch windows	Population Council	Population Council	N/A
MTN 034 program on laptop		Data management security: needed to correct MTN-034 data	Population Council	Population Council	N/A
SCHARP Atlas portal		Data transfer security: Needed to upload data to SCHARP via Atlas portal	Email addresses of data managers will be registered in Atlas by SCHARP	Assigned by SCHARP	N/A
Tablet computer	Tablet Administrators	Device security: needed to unlock tablet	N/A	N/A	Default is dvd15; Each Tablet Administrator will reprogram his/her tablet and select his/her own PIN
MTN 034 App		MTN-034 App security: needed to open MTN-034 App	3-digit ID assigned by site Data Manager from the range of IDs for each site	N/A	N/A
MTN-034 Survey	ACASI Interviewers	MTN-034 Survey security: needed to set up and initiate survey for participant	3-digit ID assigned by site Data Manager from the range of IDs for each site	N/A	N/A

Data Manager

The site Data Manager will have 4 sets of IDs/passwords:

- PIN to unlock laptop computer** – The Population Council will provide the PIN to each data manager so that s/he can unlock the laptop computer.
- Windows login name/password to be assigned by Population Council** – This user ID and password will enable the Data Managers to launch Windows. After entering the PIN, the laptop will boot up. A screen will appear where the Data Managers can enter user name and password to launch windows. All Data Managers will use “Investigator” as the User Name. The password will be provided to Data Managers during or after ACASI training.
- User name/password to change data** – The Data Manager will be assigned a user name and password to change data. The Population Council will assign the user name as the first initial of the Data Manager’s first name and the full last name. The Population Council will assign a unique password to the Data Manager.

The user ID and password to change data will be DIFFERENT from the PIN required to unlock the laptop, or the password needed to launch windows.

The Data Manager will need to enter this user name and password into the MTN-034 program on the PC to be able to change any data (visit date, PTID), which would only occur based on instructions from SCHARP. If a password needs to be changed or a new Data Manager is identified, the Population Council will need to update the database to enter the new user name(s) and password(s).

4. **ATLAS/SCHARP user names/password to submit data to SCHARP** – Data Managers will email SCHARP to be assigned a password. Data Managers’ email addresses will be their user IDs for logging into the ATLAS portal. Data Managers will need their User ID and the password assigned by SCHARP to upload data to the secure ATLAS portal at SCHARP.

Tablet Administrator

Each Tablet Administrator will be responsible for one specific tablet that s/he will have for the entire study. Each Tablet Administrator will have a 3-digit **Administrative ID** (Admin ID) and a 4-digit **PIN** (Personal Identification Number).

Admin ID: The Admin ID will be a 3-digit number assigned by the Data Manager at each site from the range of IDs available per site (see Table 2). Tablet Administrative IDs will be the FIRST 3 IDs from the range of IDs, e.g. 111, 112, 113.

Table 2 – Tablet Administrator and Interviewer IDs and Study Sites

Site Name	Tablet Admin ID Range	ACASI Interviewer ID Range
Practice Site	100-110	100-110
MU-JHU Uganda CRS	111-113	114-120
Spilhaus CRS	121-123	124-130
Emavundleni CRS	131-133	134-140
Kisumu CRS	141-143	144-150
Wits RHI CRS	151-153	154-160

For Tablet Administrators who are also interviewers, the same 3-digit ID will be used for both roles.

PIN: During testing, Tablet Administrators will use the default PIN to unlock the tablet. Once testing has been completed and sites are ready for activation, Tablet Administrators will select their own unique 4-digit PINs that only they will know. Each Tablet Administrator will write down her/his PIN and seal it in an envelope that will only be opened if the PIN is forgotten or the study staff member leaves the site. (See Appendix C for steps to follow if the PIN is forgotten.)

To set up the unique PIN to unlock the tablet:

- Touch **Settings** at the top of the tablet, on the right side  or at the bottom of the screen .

- Touch **Lock Screen and Security** on the left menu (Figure 7).

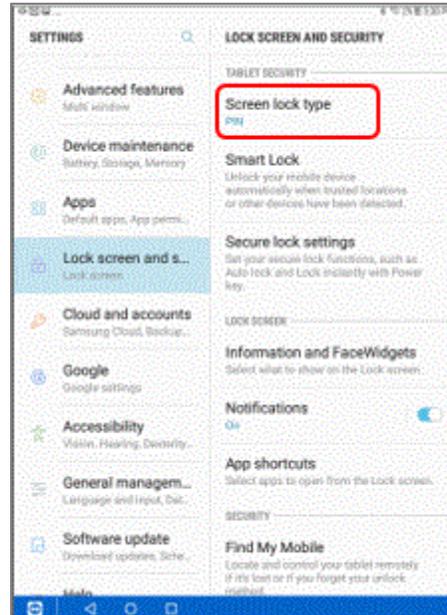


Figure 7 - Screen Lock Options

- If the screen says something other than “PIN” under **Screen lock type** on the right (Figure 7), touch **Screen lock type** and then touch PIN to set your own 4-digit code (Figure 8A and B).

Note: If the tablet is already set to use a PIN, an administrator can change the PIN by touching “PIN” to set his/her own 4-digit code, but s/he will also need to know the current PIN.

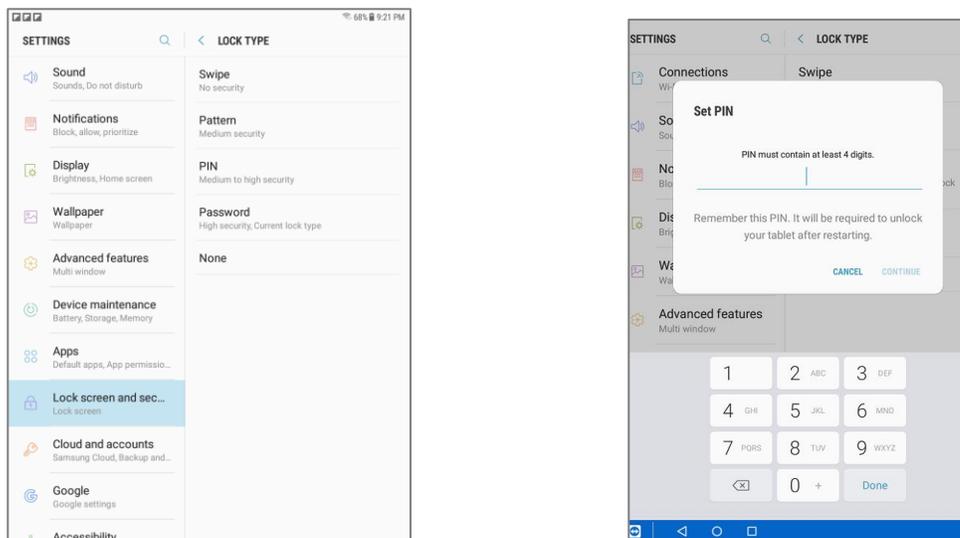


Figure 8 - Set PIN Screen A and Screen B

- Type in a 4-digit PIN and press Continue.
- For future logins, the screen will look like the picture below when it is locked (Figure 9):

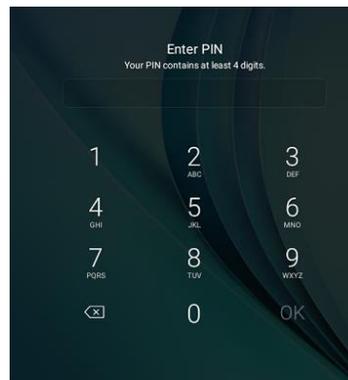


Figure 9 - Enter PIN after Customizing

- Once the PIN has been selected, the Tablet Administrator must remember the PIN and not share it with anyone. The Tablet Administrator will write down the PIN on a piece of paper and seal it in an envelope. The envelope will be stored by the Data Manager and will not be opened unless the PIN is forgotten, or the Tablet Administrator leaves the site (and a new Tablet Administrator is to be assigned).

ACASI Interviewer

Each ACASI Interviewer (Interviewer) will have her/his own Admin ID, to be assigned by the Data Manager from the list of available Admin IDs per site (see Table 2 for list of sites and associated Admin IDs). The Data Manager will assign the numbers to the interviewers and keep a record of which Admin IDs have been used. The Data Manager will submit a signed, dated ACASI-REACH-SOP login form to the Population Council prior to site activation. Any changes will be documented on an updated, signed form.

- If one person is both a Tablet Administrator and an Interviewer, s/he should only use the tablet that was assigned to him/her. S/he will first use the PIN s/he created to unlock the tablet, S/he will then enter the 3-digit Admin ID assigned by the Data Manager.
- Study staff to whom ACASI Admin IDs, passwords, and/or PINs are assigned should not share this information with anyone else.
- Once the tablet has been set up, press the back arrow button on the bottom of the tablet to return to the home screen (see Figure 3).

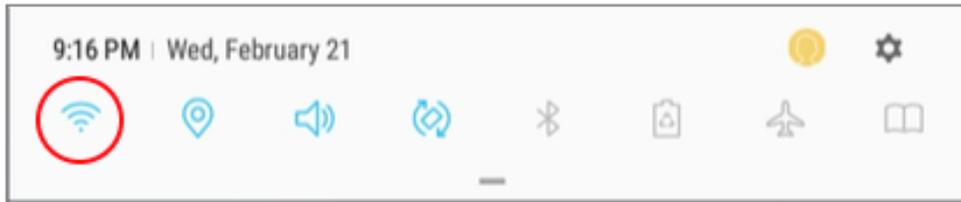
6. SETTING UP THE TABLET FOR SURVEYS

The first time the App is run, the Tablet Administrator will need to check for application updates via WiFi. During the study, Population Council staff will alert study staff at the MTN-034 sites if the App needs to be updated.

Other than when updating the App, the WiFi must be off.

Updating the App:

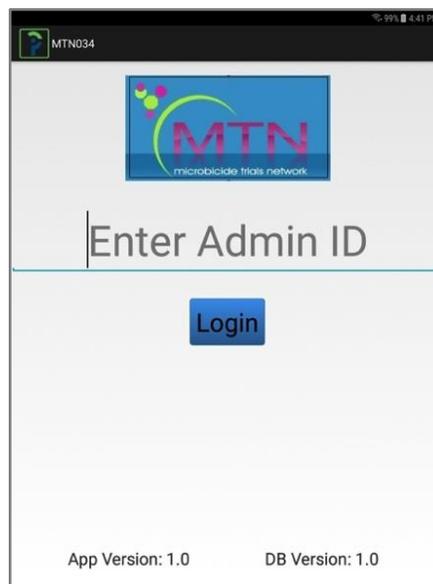
1. To turn the WiFi on or off, touch **Settings** (top of the tablet, on the right side  or at the bottom of the home screen ).
2. Touch the top of the display to bring down the toolbar shown below, then touch the first icon.



3. Once the WiFi is on, return to the home screen and press the MTN-034 icon on the tablet's home screen.

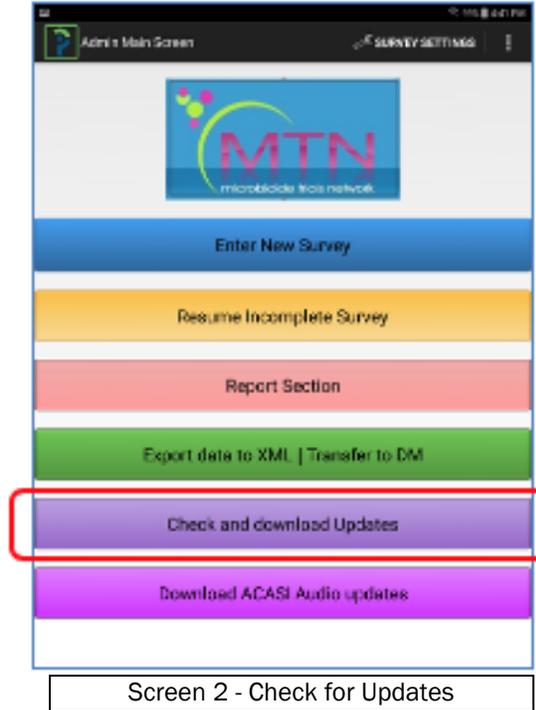


4. Next, the Tablet Administrator will enter her/his ID, using the cursor and typing in the 3-digit ID assigned by the Data Manager. Then press Login (Screen 1).

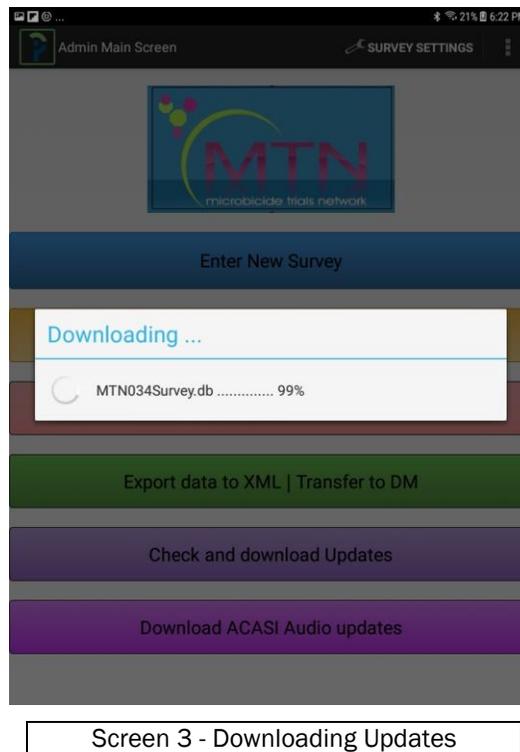


Screen 1 - Tablet Admin Login

5. The Admin Main Screen will be the first screen that appears once you Log in. The first thing you will do is press the purple button (second from the bottom) “Check and download Updates” (note: an error message will occur if the tablet is not connected to the internet).



The screen will look like the one below while updates are being downloaded (Screen 3).

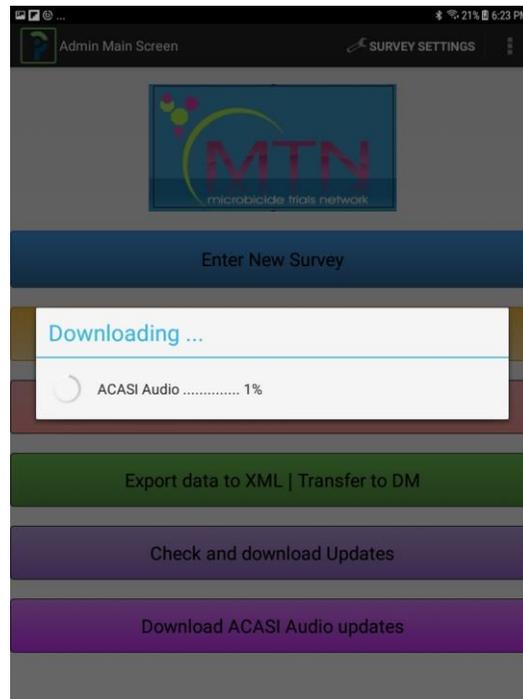


6. Next, touch Download ACASI Audio updates for the latest version of the audio files (Screen 4).



Screen 4 - Check for Audio Updates

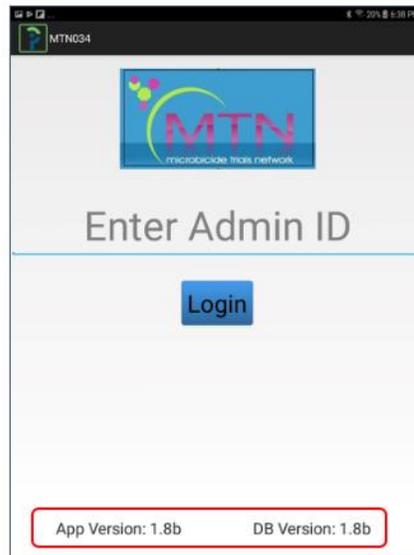
The screen will look like the one below (Screen 5) while ACASI audio updates are being downloaded.



Screen 5 - Audio Updates Downloading

7. Next, return to the settings menu to **turn off WiFi**, once the downloads have completed.

8. From the home screen, note the App. Version number is updated to the correct number that Population Council have requested (Screen 6).



Screen 6 - Check App Download

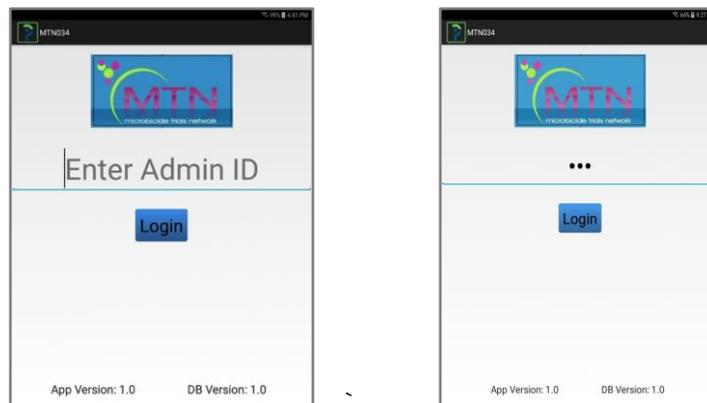
7. ADMINISTRATIVE SETUP

First, the **Tablet Administrator** will be prompted to enter his/her ID to open the App. Once the App is opened, the Tablet Administrator gives the tablet to the **ACASI Interviewer** who will complete the administrative set up for each interview.

If the Tablet Administrator and the ACASI Interviewer are the same person, she will complete both tablet administrator log-in and interviewer survey set-up activities, as described below.

Log-in: Tablet Administrator

- Type in the 3-digit Tablet Administrator ID assigned by the Data Manager. The numbers will be masked as you type them in (they become bullets, as show on the screen to the right below).
- Touch the blue 'Login' box to login.



Screen 7 - Enter Admin ID

Survey set-up: ACASI Interviewer

Once logged in, you will see the Admin Main Screen. From this screen, you will need to choose the survey type: new or incomplete. A new survey is one that has not yet been started. An incomplete survey is one that a

participant began, but that was stopped before she completed the survey for any reason (other than the participant declining to continue with the interview). An incomplete survey can be resumed on the same day that it started or on a later date (see Section 7B for instructions on resuming an incomplete survey).

7A. SETTING UP A NEW SURVEY

1. To set up to start a new survey, touch the top blue bar, “Enter New Survey” (Screen 7).



Screen 8 - Enter New Survey

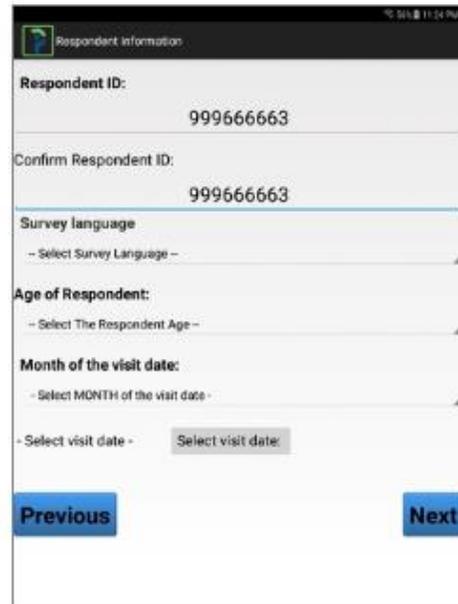
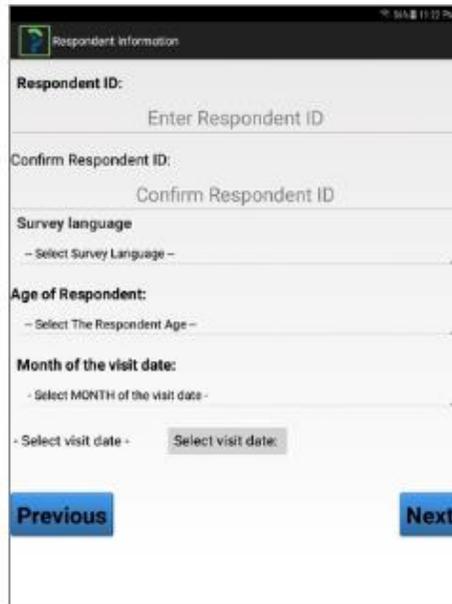
2. Select site name from the drop-down menu (Screen 9).
3. Select the assigned Interviewer ID from the drop-down menu (Screen 9) and press NEXT.



Screen 9 - Select Site Name and Interviewer ID

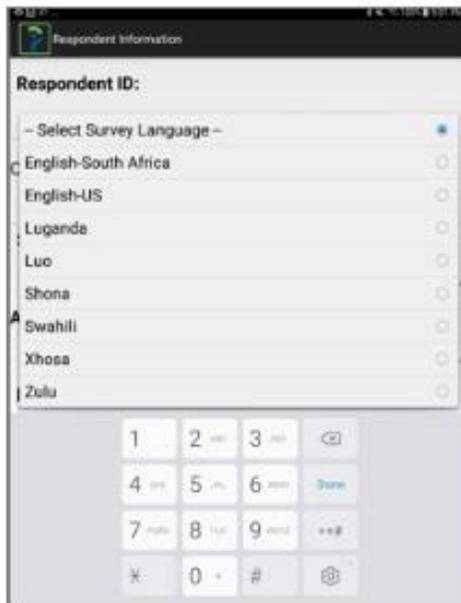
NOTE: study staff members who are both the Tablet Administrator and the Interviewer will select the **SAME 3-digit ID** from the drop-down menu that was used to open the App. Interviewers who are **NOT** also tablet administrators will need to select their unique 3-digit Interviewer ID from the drop-down menu.

4. Next, enter the Respondent ID (PTID) by typing in the 9-digit number and then enter the same number where it says “Confirm Respondent ID” (Screen 10). It is not necessary to enter hyphens/dashes, just the digits.



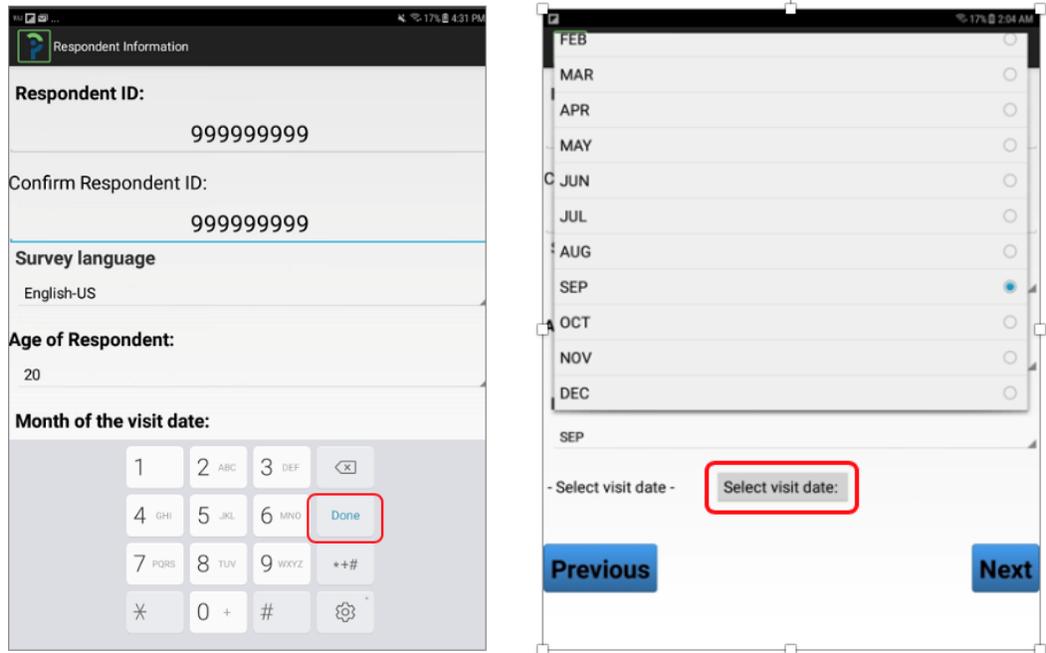
Screen 10 - Enter and Confirm Respondent ID

5. Survey Language – Select the survey language from the drop-down menu (Screen 11, left).
6. Age – Select the age of the participant (on the day of her interview) from the drop-down menu (Screen 11, right)



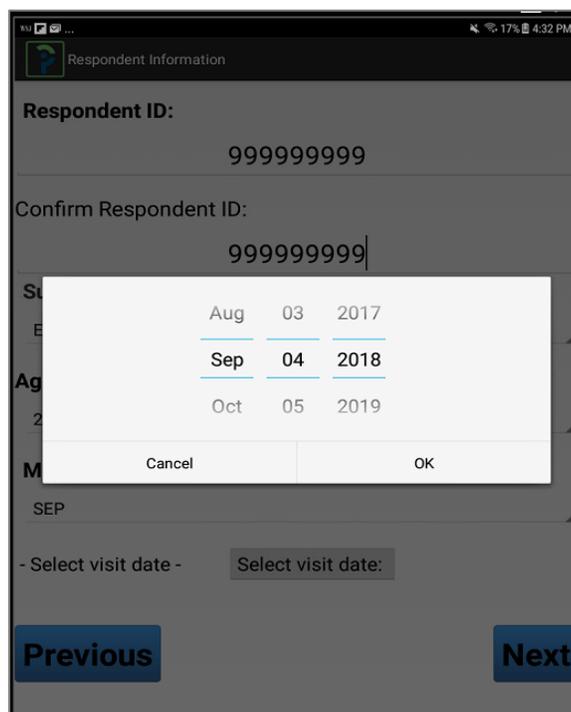
Screen 11 - Select Month of Visit, then select Age

7. Once you have entered the respondent ID, language and age of respondent, press “DONE” on the keypad as shown in Screen 12 on the left.
8. Month – next select the Month of the visit date from the drop-down menu, (Screen 12 at right).



Screen 12 - Select Month of Visit

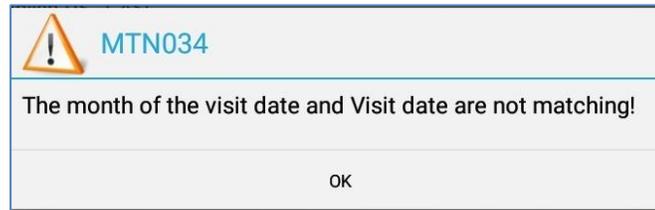
9. Date – next touch the grey bar, “Select visit date” (shown in Screen 12 on the right) which should automatically fill in the exact date. Check the date and make any corrections; then click OK as shown in Screen 13.



Screen 13 - Select Exact Date

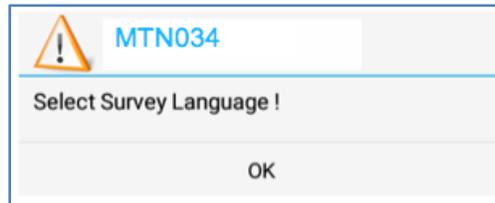
10. After completing the respondent information, touch the Blue ‘NEXT’ box.

NOTE: The date MUST MATCH MONTH SELECTED ABOVE or an error message will appear (Screen 14):



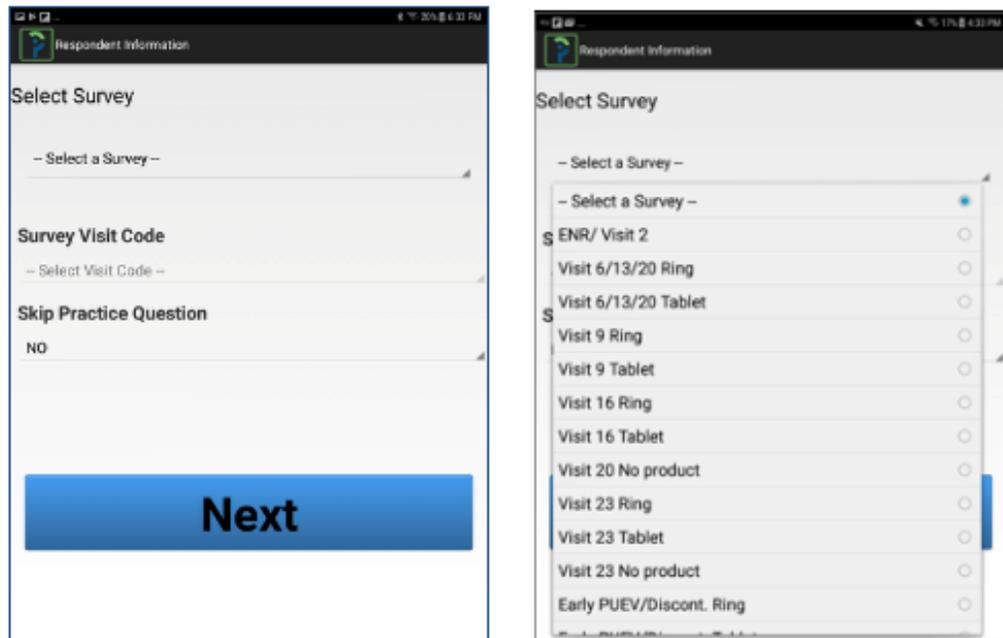
Screen 14 - Error with Date Mismatch

NOTE: Values must be chosen for all fields or an error message will appear (Screen 15):



Screen 15 - Error No Language Selected

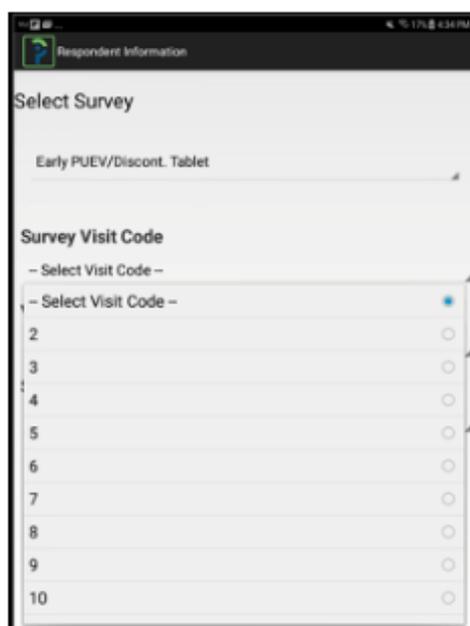
11. Next, go to “Select a Survey” and choose the survey you wish to administer from the drop-down menu (Screen 16, left).



Screen 16 - Survey Drop-down list

12. Then select the “Survey Visit Code” from the drop-down menu (Screen 17).

NOTE: Some surveys are used for multiple visits, so it will be important to choose the correct visit code. Some surveys (like enrollment) can only be used at one specific visit, so the Visit code (2.0) is the only option to select. Refer to Table 3 below for the list of all visits at which ACASI interviews are administered, the correct survey to use at each visit, and instructions about which visit codes to use.



Screen 17 - Select Visit Code

Table 3 - Visit Schedule, Survey Name and Visit Codes for ACASI REACH

Visit	Regimen	Survey name	Visit Code(s)	When Used (See SSP Section 1.1 for more details)
Enrollment (Visit 2)	Ring or Tablet	ENR/Visit 2	2.0	Only used at Enrollment visit – all participants complete the same survey regardless of randomization/regimen
Visit 6	Ring	Visit 6/13/20 Ring	6.0	The same survey is used at Visits 6, 13 and 20. The Visit Code will identify the visit. Select Ring or Tablet based on the product the participant used just before the visit.
	Tablet	Visit 6/13/20 Tablet		
Visit 9	Ring	Visit 9 Ring	9.0	These surveys are only used at Visit 9. Select Ring or Tablet based on the product the participant used just before the visit.
	Tablet	Visit 9 Tablet		
Visit 13	Ring	Visit 6/13/20 Ring	13.0	The same survey is used at Visits 6, 13 and 20. The Visit Code will identify the visit. Select Ring or Tablet based on the product the participant used just before the visit.
	Tablet	Visit 6/13/20 Tablet		
Visit 16	Ring	Visit 16 Ring	16.0	These surveys are only used at Visit 16. Select Ring or Tablet based on the product the participant used just before the visit.
	Tablet	Visit 16 Tablet		
Visit 20	Ring	Visit 6/13/20 Ring	20.0	The same survey is used at Visits 6, 13 and 20. The Visit Code will identify the visit. Select Ring or Tablet based on the product the participant used just before the visit.
	Tablet	Visit 6/13/20 Tablet		
	No Product	Visit 20 No Product		
Visit 23	Ring	Visit 23 Ring	23.0	This survey is used only for participants using the Ring in the period before Visit 23.
	Tablet	Visit 23 Tablet		This survey is used only for participants using the Tablet in the period before Visit 23.
	No product	Visit 23 No Product		This survey is used only for participants who are not using either product (neither Ring nor Tablet) in the period before Visit 23.
Any visit	Ring	Early PUEV/Discontinuation Ring	2.0-22.9	This survey should be used for participants who are permanently discontinued from both products (i.e. due to seroconversion or

	Tablet	Early PUEV/Discontinuation Tablet		<p>pregnancy) or terminate early from the study (before Visit 23). Select Ring or Tablet based on the product the participant used just before the discontinuation or termination. See SSP Section 11 for more details.</p> <p>If the participant discontinues at a scheduled monthly visit, the Survey Visit Code will correspond to that visit (3-22). The "Visit Code interim" value should be "0." If the participant discontinues at an interim visit, the Survey Visit Code will be the code of her last visit prior to the decimal point, and the Visit Code Interim visit should be the number after the decimal point. . For example, if the participant takes the Early PUEV/Discontinuation survey at visit 11.2, enter "11" under "Survey Visit Code" and "2" under "Visit Code interim" (see Screen 17 on page 22).</p>
Any visit after Visit 16	No product	Early PUEV/Discontinuation No Product	16.1-22.9	<p>This survey should be used during study Period 3 for participants who have chosen not to use a product and who are permanently discontinued from both products (i.e. due to seroconversion or pregnancy) or terminate early from the study (before Visit 23). See SSP Section 11 for more details.</p> <p>For participants who have chosen neither product and are discontinuing, the Visit Code should be 16-22. The "Visit Code interim" value should be "0." If the participant discontinues at an interim visit, the Survey Visit Code will be the code of her last visit prior to the decimal point, and the Visit Code Interim visit should be the number after the decimal point. For example, if the participant takes the Early PUEV/Discontinuation survey at visit 17.2, enter "17" under "Survey Visit Code" and "2" under "Visit Code interim."</p>

13. Practice Questions – after completing all participant and visit information, you are ready to go to the survey. For all participants at their enrollment visits, the interviewer must teach the participant how to use the App using the practice questions. Therefore, where it says "Skip Practice Question" as shown in Screen 18 below, the answer should be "No." Participants can do the practice questions at any visit if they feel it's helpful.

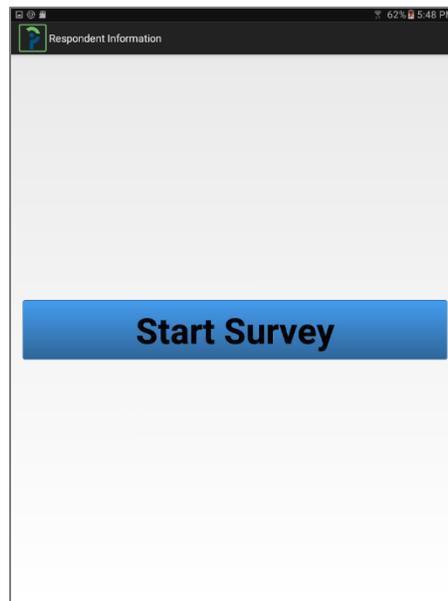
The screenshot shows a mobile application interface titled "Respondent Information". It contains three dropdown menus. The first is labeled "Select Survey" and has "ENR/ Visit 2" selected. The second is labeled "Survey Visit Code" and has "2.0" selected. The third is labeled "Skip Practice Question" and has "NO" selected. At the bottom of the screen is a large blue button with the word "Next" in white text.

Screen 18 – Choose or Skip Practice Questions

14. If the participant does not need additional practice (to be determined by the Interviewer together with the participant), select “Yes” from the drop down-menu. At subsequent visits, if the Practice Questions are not necessary (to be determined by the Interviewer together with the participant), click “YES” from the drop-down menu and the Practice Questions will be skipped and go directly to the survey.

NOTE: “No” (meaning, do NOT skip the practice questions) is the default answer to the question. If you do not press “Yes,” the survey will start with the practice questions. If it was not your intention to do the practice questions, there is no way to go back and start again. Therefore, it is better to do the extra practice questions rather than quitting out of the survey and starting a new one.

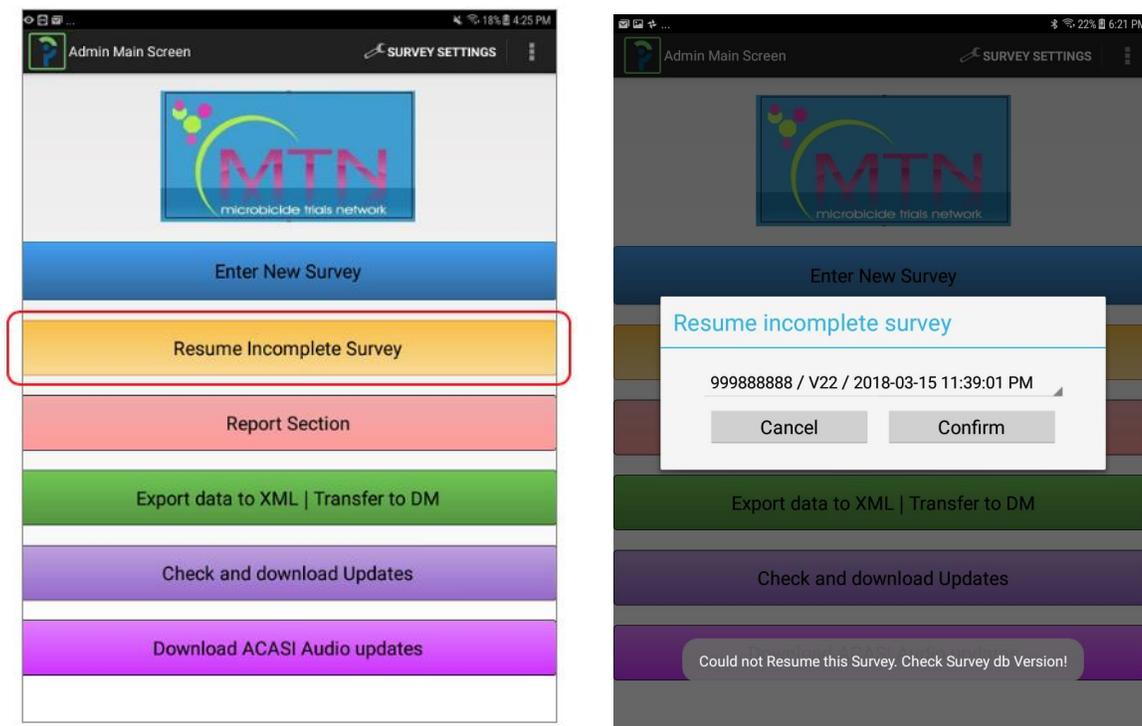
15. Then touch “Next” and **STOP** at the screen below.



Screen 18 - Ready to Start Survey

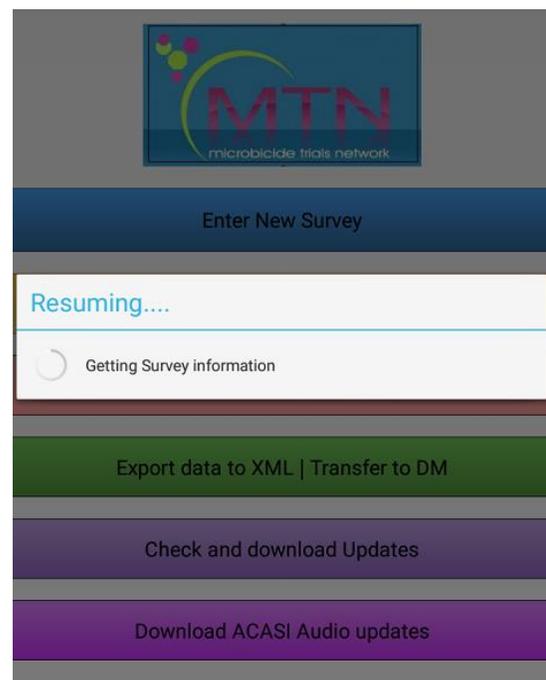
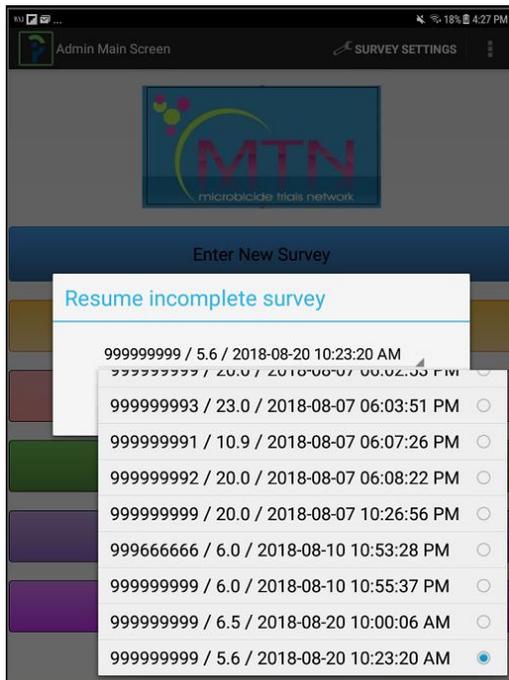
7B. RESUMING AN INCOMPLETE SURVEY

1. If you are continuing a previous survey, touch the second bar on the Admin Main screen (Screen 20). (Please refer to the Section 11.2.6 of the MTN 034 SSP for instructions on when incomplete surveys should be resumed or when a new survey is required.)



Screen 20 - Resume Incomplete Survey

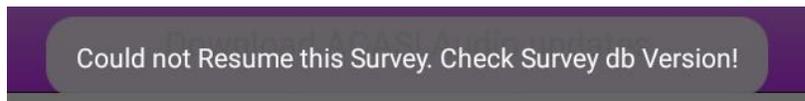
2. When you press “Resume Incomplete Survey” you will see a pop-up box asking you to “Cancel” or “Confirm” (see Screen 20). If you pressed “Resume Incomplete Survey” accidentally, press “Cancel” to be taken back to the Admin Main Screen.
3. To proceed to the incomplete survey, press “Confirm.”
4. Once you press confirm, you will see a list of incomplete surveys to choose from (Screen 21, left side). Use your finger to choose the appropriate survey to resume.



Screen 21 - Choose Survey to Resume

- When you click on the survey you wish to resume, the App will go to the next unanswered question from the incomplete survey. You will see “Getting Survey Information” while the App is searching for the correct question in the survey to jump to (Screen 21 at right).

If you see the message below, it means the App has been updated since the participant started the survey. You will not be able to resume the survey and the participant will need to start a new survey with current version of the App.



8. SETTING UP THE PARTICIPANT

After the tablet has been prepared, the participant will need to be trained to use the App using the Practice Questions. See Appendix A for a sample script of how to train the participant.

Using the Tablet

Try to make the participant feel as comfortable as possible prior to introducing her to the actual process of the ACASI interview. Explain to her that what she is being asked to do on the tablet is limited and might be easy and fun. Further explain that she will be taught everything she needs to know to use the tablet.

Touch screen training

The nature of the tablet touch-screen should be explained to the participant. If necessary, an analogy using a cell phone might be useful. For instance, pressing or touching a smart phone screen is similar to touching options on the tablet screen. Explain to the participant that she does not need to press hard on the screen with their fingers – a soft touch is enough to record the information.

This explanation may not be needed if the participant has used a smartphone.

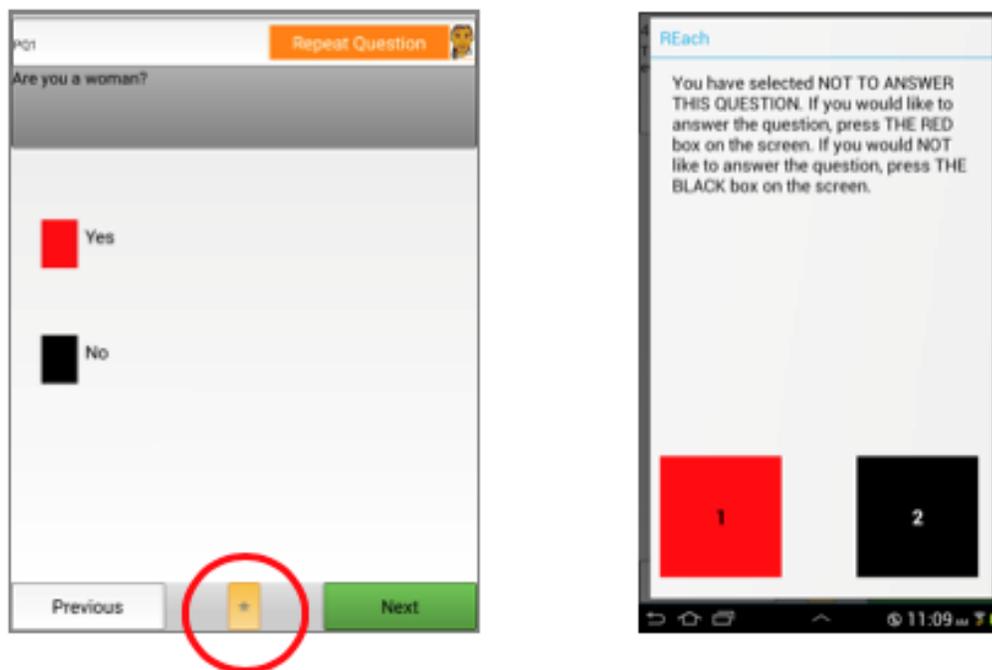
9. PRACTICE QUESTIONS

Explain to the participant:

1. That you will now show her how to use the tablet to answer questions.
2. That there will be six questions for practice and that you will sit with her during those six questions to make sure she fully understands how to answer the questions using the tablet.
3. That you will not remain with her during the regular interview because we want her to answer the questions comfortably and in private.

It is recommended that the interviewer goes through all of the practice questions together with the participant, listening together, without headphones. Then, when the participant starts the survey or repeats the practice questions by herself, she should use the headphones.

- Show the participant where on the screen the text of the question can be read (gray box at the top).
- Explain that after the participant has selected an answer, she can proceed to the next question by pressing/touching the green box at the bottom right that says **Next**.
- Explain that if she would like to return to the previous question, she should press the white box on the bottom left hand side of the screen that says **Previous**.
- Explain that if the participant has any other problems or would like to stop the interview for any reason, she should let you know. (Advise the participant where to find you.)
- Explain that the orange star button at the bottom middle of the screen will enable her to skip any question she does not want to answer in the actual survey, although it is not functional in the practice questions. Screen 22 illustrates the SKIP icon and the pop-up message box that a participant will see if she presses the “Skip” button during the actual survey.



Screen 22 - Skip Question and Pop-up Message

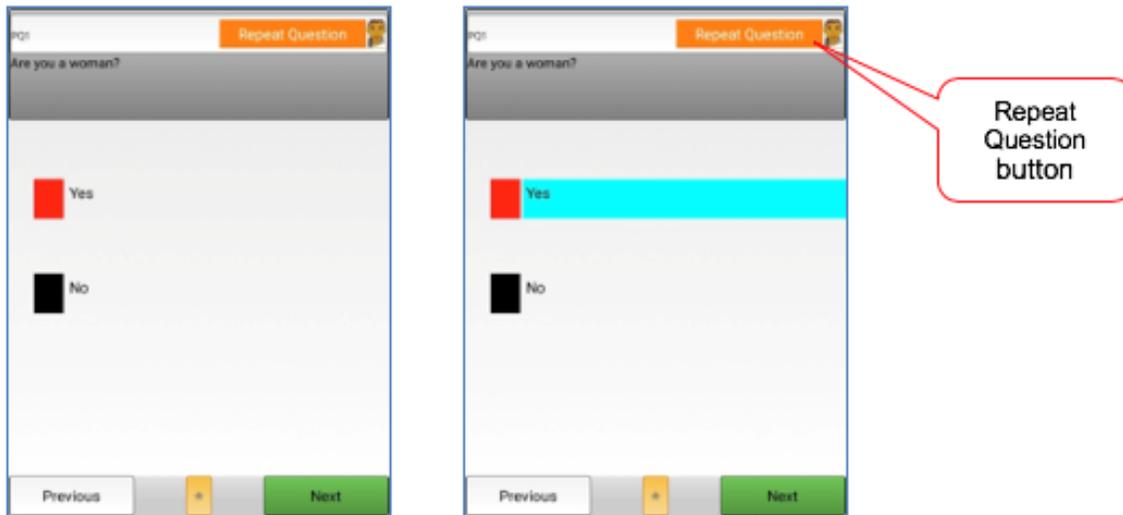
- Ask if the participant has any questions. If there are no more questions, ask the respondent to press the picture of the woman at the top of the screen (or the Repeat Question box) to re-ask the first practice question. The participant can then select the appropriate answer and proceed to the next practice question. Monitor her progress through the practice questions and her ability to answer the first three

questions (sex, age, number of children) correctly. Sit next to the participant while she answers the practice questions. If necessary, the practice questions can be repeated.

- Let the participant read and listen to the introductory text before proceeding. Explain that there may be introductions like this in several points of the survey, between sections. After she has read and listened to it, instruct the participant to touch **Next** to proceed.

There are 6 Practice Questions that will give participants the opportunity to see the different question types before they start the actual survey:

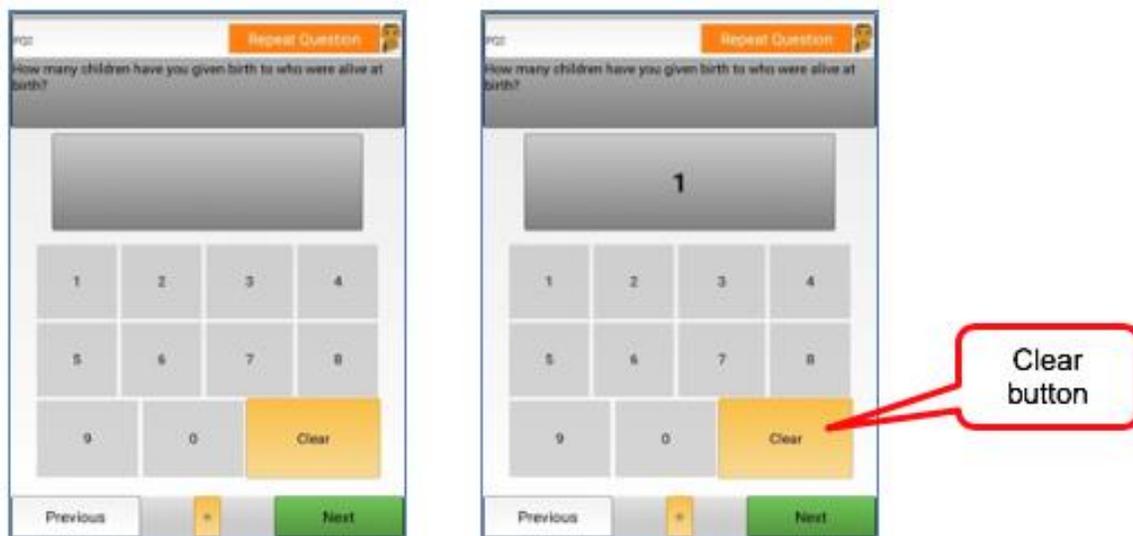
PQ1 – Are you a woman? Touch the red box if Yes or the black box if No, then touch **Next** to continue to the next question. Note: she must enter “Yes” to this question or an error message will pop up.



Screen 19 - PQ1 and Repeat Button

The purpose of this practice question is for the Interviewer to be sure she understands with a question that has a clear “Yes/No” answer. This is also a good opportunity for the interviewer to show the participant how to repeat a question by pressing the orange “Repeat Question” bar. It can also be used to show the participant an example of an error message if she presses “No.”

PQ2 – How many children have you given birth to who were alive at birth? Touch the numbers on the screen to enter your response, and then touch **Next** to continue to the next question.



Screen 204 - PQ2 Number Keypad

The purpose of this question is to show the participant how to enter numbers, clear numbers if she makes a mistake, and re-enter a correct number. She can also press “Repeat Question” to clear her answer if she makes a mistake.

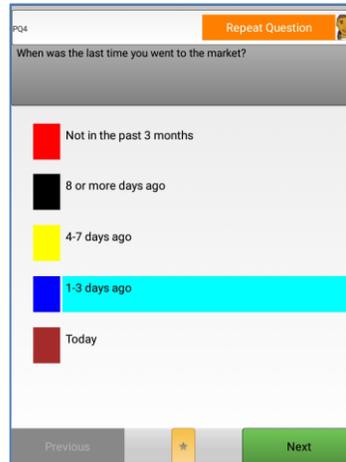
PQ3 – What is your age? Choose your response and then touch **Next** to continue to the next question. NOTE: Response must correspond to the age entered in the Admin Set-up for the survey or an error message will pop up.



Screen 21 - PQ3 Multiple Choice

The purpose of this question is to make sure she can pick out the correct category.

PQ4 – When was the last time you went to the market? Choose your response and then touch **Next** to continue to the next question.



Screen 22 - PQ4 Multiple Choice

The purpose of this question is to demonstrate multiple categories.

PQ5 – How difficult is it for you to get to the market? Choose your response and then touch **Next** to continue to the next question.



Screen 237 - PQ5 Multiple Choice

This question is a follow up to the previous question and demonstrates an objective question (when) followed by a Likert type question (how difficult). Furthermore, this question is to demonstrate the need to scroll in longer questions. The interviewer should demonstrate to the participant that the full question doesn't appear in the grey area on the top of the screen and that there will be cases where she will need to scroll to see the complete question.

PQ6 – How did you get to the clinic today? Touch the screen to enter your response, and then touch **Next** to begin the survey.

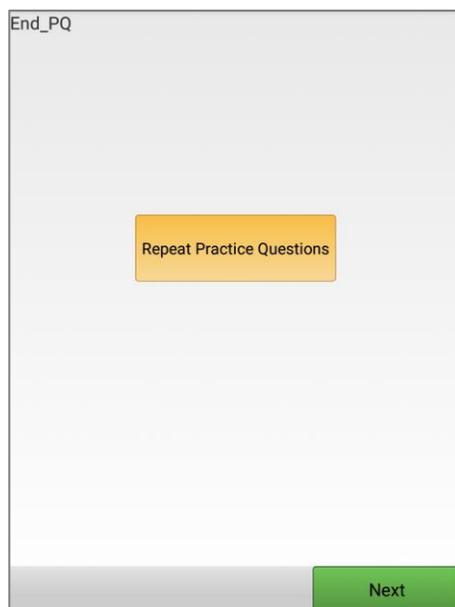
For this question, you may select more than one response.



Screen 24 - PQ6 - Choose Multiple Responses

The purpose of this question is to demonstrate that it is possible to select more than one response and to practice deselecting a response by pressing it a second time for any question that allows multiple responses (i.e. “mark all that apply”).

- 4. After the participant has completed the practice questions, she can repeat them or go to the survey.
- 5. If the participant wants to or needs to repeat the practice questions, touch the "REPEAT PRACTICE QUESTIONS" button. Select this option if you think the participant needs more practice before beginning the survey.



Screen 25 - Repeat Practice Questions

6. Once the participant is ready to proceed to the actual survey, explain that she is ready to start the survey and you will now leave the room for her to be able to answer the questions privately.
7. Make sure she is ready to begin by ensuring her headphones are working, she has privacy, and she feels ready to begin.
8. Touch the green NEXT button to start the survey and leave the room.

Once the participant has completed the practice questions the Interviewer must leave the room before she starts the survey.

The Interviewer should wait near the interview room to be available if participants have any questions or problems. The interviewer may need to respond to specific questions the participant may have about the interview questions. Note that the majority of participant questions may be about the content and meaning of the questions. Therefore, interviewers must have a good understanding of the meaning of each question.

Participants who are unable to use ACASI

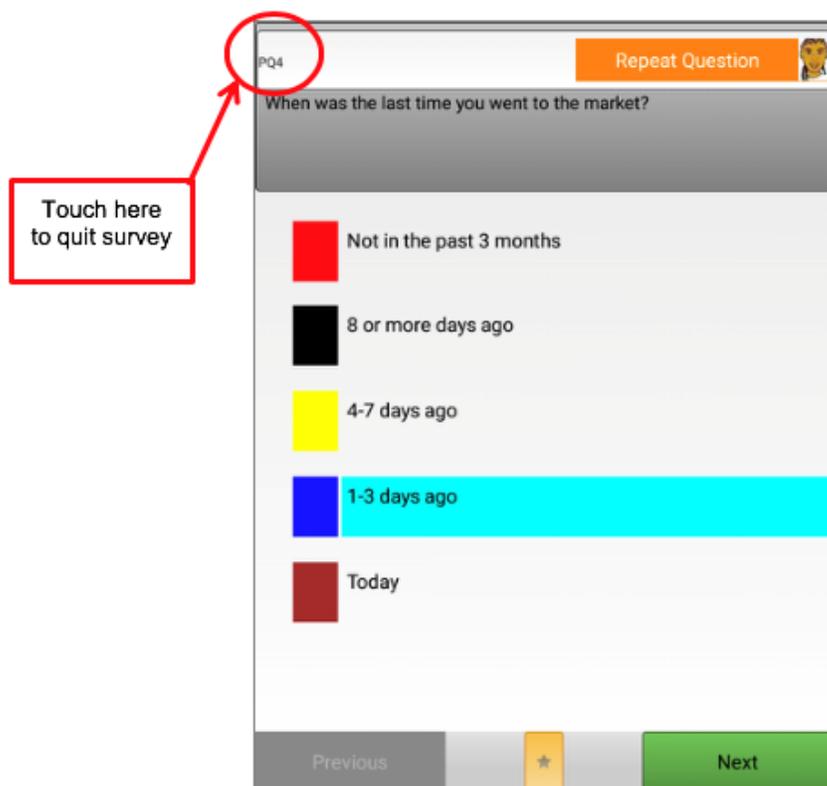
If a participant is willing to use ACASI but cannot because she lacks numerical literacy or is otherwise unable to correctly use it after several attempts with the practice questions, do not have her complete the ACASI Questionnaire. The decision to not do the ACASI interview is at the discretion of the site staff/investigator. Document in the participant's chart notes that she is unable to complete the questionnaire and specify the reason(s). On the ACASI Summary CRF (see SSP 11.2.5), indicate that the participant did not complete the specified ACASI Questionnaire and record the reason it was not completed in the text box provided.

10. EXITING THE ACASI PROGRAM

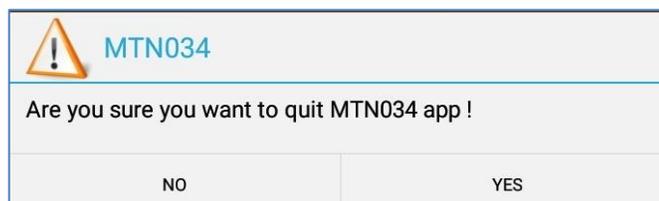
Exiting the ACASI Program

After a complete survey is successful (i.e. all answers have been correctly saved), the App automatically resets to a login screen to start a new survey.

At any time, the ACASI Tablet Administrator or ACASI Interviewer can exit the MTN-034 app by touching the top left corner of the screen where the question number appears as close as possible to the outer edge of the screen (Screen 30). A grey box will pop up, asking if you would like to exit the survey (Screen 31). (Note: during the administrative setup, double tapping on the MTN-034 logo exits the App.)



Screen 30 - Quit Survey Before Finishing



Screen 31 - Confirm Quit App/Survey

Reasons for exiting the App in the middle of an interview could include:

- Participant needing to leave before completing the interview (for time/logistical reasons vs unwillingness to complete the survey)
- Emergency at study site requiring evacuation

If the App was terminated by the ACASI Tablet Administrator or Interviewer for any reason that is not a survey selection error, the participant could resume the survey when she is ready to resume. If the App was terminated by the ACASI Tablet Administrator or Interviewer to quit the APP for any reason that is not a program or tablet error, the participant could resume the survey when she is ready to resume. The App will save all data entered until you quit out of the App. Surveys that were stopped by exiting out of the App before being completed can be

resumed by selecting “Resume Incomplete Survey” as outlined in Section 7B (Screen 20). Refer to SSP Section 11.2.6 for details on when to resume an incomplete survey or begin a new one.

Tablet/Program Failures

If the App fails due to program or tablet error, the Tablet Administrator will need to restart the tablet and the data from the incomplete survey will not have been saved. In this case, the participant will need to start a new survey. The App will allow one study participant to complete a survey more than once, but the data from each survey will be saved separately.

If there are any program or tablet 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 App to stop, exit the program and restart the tablet and re-login to the program. Email the description of the problem to MTN034ACASI@mtnstopshiv.org.

11. REPORTS AVAILABLE ON ACASI TABLETS

Reports are used to track and see what surveys were conducted on a specific tablet. They are usually used by the Tablet Administrator or Data Manager to ensure that all survey data has been exported and can be run any time at the Data Manager’s discretion.

There is also a counselling report that must be run by the Interviewer at the end of each ACASI survey. The list of reports allows filtering by date, using the Visit Date field.

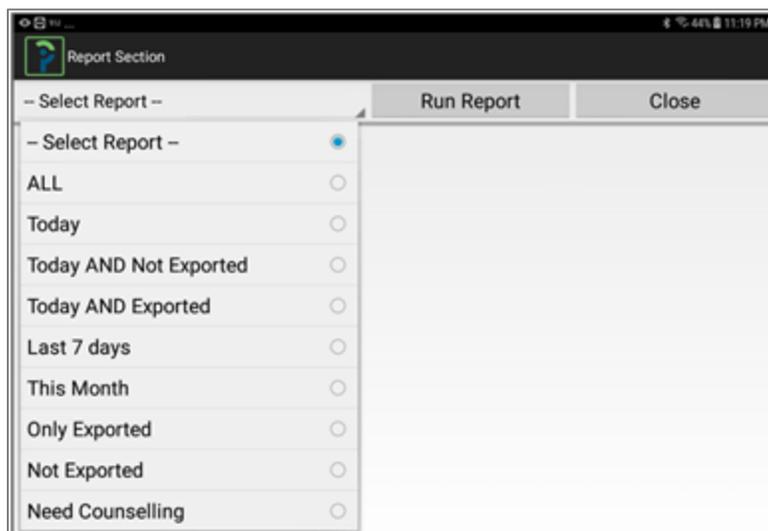


Figure 10 - Select Report

Report options

Figure 10 illustrates the 9 different reports that can be run from the tablet:

- ALL => show all survey files in this tablet.
- Today => show only the surveys that were conducted today, based on the visit date.
- Today and Not Exported => show only surveys conducted today, but not yet exported to Data Manager laptop.
- Today and Exported => show only surveys conducted today and exported to Data Manager laptop.
- Last 7 Days: show all surveys conducted in the last 7 days.
- This month: show all surveys conducted in the current calendar month (i.e. June, July, August).

- Only Exported => show all reports that were exported from this tablet.
- Not Exported => show all reports that were not exported from this tablet.
- Need Counselling => show all participants who answered AF1 = YES, needs counselling (Figure 11)

Question AF1 asks the following: We have asked you a number of questions today. Some of them may have caused you to feel worried or sad. Would you like to talk to someone about how you are feeling? If you answer yes, a counselor will be notified that you would like to talk to her or him. **This report should be run after each ACASI survey. If the participant answered Yes to question AF1, follow site SOPs to refer her to a study counselor.**

Report Section

Need Counselling Run Report Close

Total record(s) : 6

Resp PTD	Survey Name	Visit Date	Age	Survey Status	Exported
999993333 / 16.0	Visit 16 Ring	2018-10-11 01:52:29 PM	21	Completed	YES
999999999 / 20.0	Visit 20 No product	2018-09-09 06:17:49 PM	22	Compl-Resu	YES
999777777 / 23.0	Visit 23 Tablet	2018-08-18 12:02:36 AM	21	Completed	YES
999666666 / 23.0	Visit 23 No product	2018-08-17 11:51:47 PM	21	Completed	YES
999444444 / 7.5	Early PUEV/ Discont. Ring	2018-08-17 11:48:06 PM	22	Completed	YES
999999999 / 20.5	Early PUEV/ Discont. No product	2018-08-14 06:28:14 PM	21	Completed	YES

Figure 11 - Counseling Report

All reports will show the same headers, as illustrated in Figure 12, but the total number of records will vary based on how many surveys match the criteria you have chosen.

Resp PTD	Survey Name	Visit Date	Age	Survey Status	Exported
999999999 / 6.0	Visit 6/13/20 Ring	2018-08-10 10:55:37 PM	22	Interrupted	NO
999666666 / 6.0	Visit 6/13/20 Ring	2018-08-10 10:53:28 PM	21	Started	NO
999999999 / 20.0	Visit 20 No product	2018-08-07 10:26:56 PM	22	Interrupted	NO
999999992 / 20.0	Visit 6/13/20 Tablet	2018-08-07 06:08:22 PM	18	Interrupted	NO
999999991 / 10.9	Early PUEV/ Discont. Ring	2018-08-07 06:07:26 PM	22	Interrupted	NO
999999993 / 23.0	Visit 23 No product	2018-08-07 06:03:51 PM	23	Interrupted	NO
999999999 / 20.0	Visit 20 No product	2018-08-07 06:02:53 PM	21	Interrupted	NO

Figure 12 - Sample Report

If you see “no Data for this selection,” it means there are no surveys that match the criteria (Figure 13)



Figure 13 - No Surveys Match Selected Criteria

10. ACASI DATA MANAGEMENT

This section explains the process the **Data Manager** will follow to export data from the tablets, import the files to the Data Manager PC, merge the files from the tablets into the database (DB) on the laptop, upload merged files to SCHARP, and back-up the data on a USB key.

Figure 14 illustrates the overall process of exporting surveys from the tablets to the Data Manager laptop, merging surveys on the laptop and uploading data to SCHARP.

1. Export files from tablets to Data Manager PC

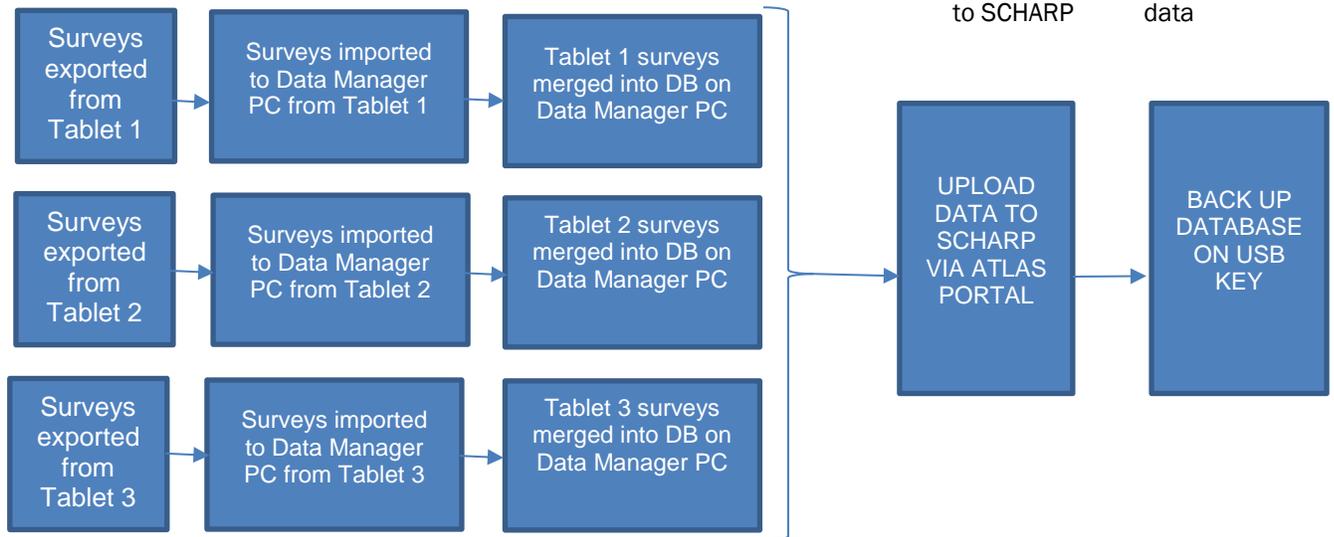


Figure 14 – Data flow from Tablets to Laptop to SCHARP

DATA MANAGER COMPUTER

The MTN-034 Data Manager laptop has an administrative home screen, similar to the Admin screen on the tablet (see Figure 16 below). This section explains how the Data Manager will export files from the tablets, import them into the data manager computer, merge files, upload to SCHARP, run reports, and edit key data, when relevant.

Exporting Files from the Tablet to the Data Manager Laptop

Each day that at least one survey is completed on a tablet, the data collected on that tablet must be uploaded to the Data Manager laptop by the Data Manager. All surveys completed that day will be uploaded to the Data Manager laptop at the end of that day. If surveys are completed on some tablets but not others, data collected on relevant tablets will be uploaded by the Data Manager each day.

The Data Manager will need to keep track of which tablets are used each day for data collection to ensure that all data collected each day on each tablet are uploaded at the end of the day.

1. Before exporting the data from each Tablet, the Data Manager should run the “Today and Not Exported” report (see Figure 10 above) by pressing the pink “Run Report” button. The report will be important for cross-checking which surveys should be in the XML file that will be transferred to the Data Manager laptop.
2. To export the data from the Tablet, the Data Manager will press the green Export Data to XML/Transfer to DM button on the Admin Main Screen of the MTN-034 App on the Tablet (Figure 15) to export it to laptop.



Figure 15 – Export Data to XML

3. You will see a message that tells you the number of surveys ready for Export (Figure 16). The number of surveys should correspond to the report run in Step 1 (and your log of surveys for the day).



Figure 16 - Confirm Surveys Exported

Importing XML Files from Tablet

1. To import files from the tablets at the end of each day, connect each tablet computer to the Data Manager laptop using the USB cable provided by the Population Council.

Note: The first time you connect the tablet and laptop, you will see a pop-up box asking if you Trust This Computer (Figure 17). You must press “Trust” when prompted to be able to transfer files from the tablet to the Data Manager computer.

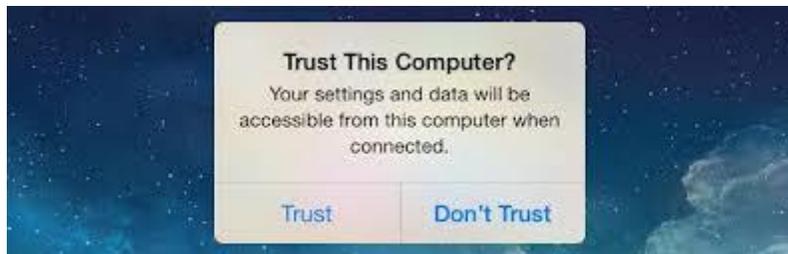


Figure 17– Trust Computer Pop-up Box

2. If the Data Manager program is not open, double click on the **ACASI Data Manager** icon on the Windows Desktop (Figure 19).
3. From the Data Manager main screen (Figure 18), click **Import XML files from the Tablet**.



Figure 18 – Import XML Files from the Tablet

4. If the files were transferred successfully, you will see a confirmation of how many files were imported (see Figure 20).
5. If no XML files were found, you will see a message saying, “No XML found” (Figure 21).
6. If the tablet is not connected to the Data Manager laptop, you will see a message saying, “Error connecting to tablet” (Figure 22).

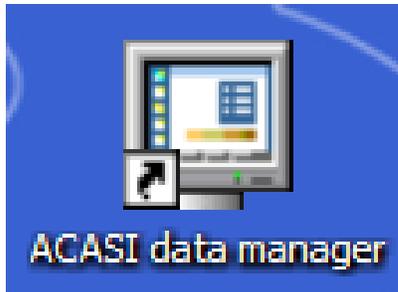


Figure 19– ACASI Data Manager Icon on Desktop

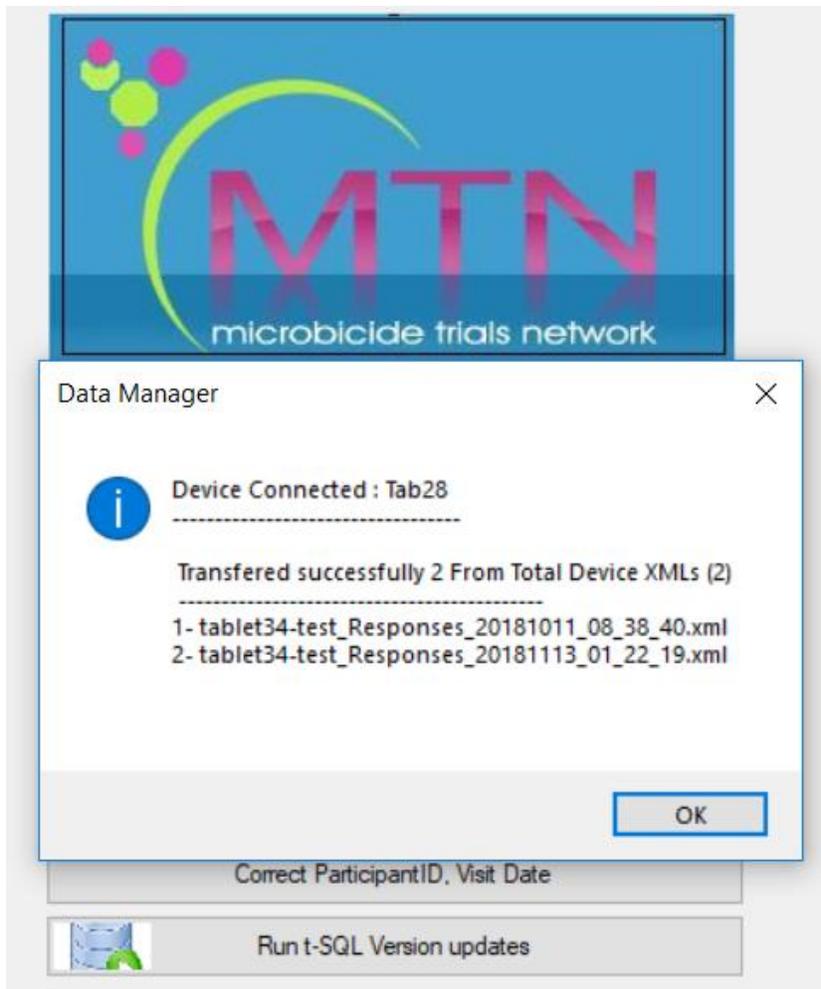


Figure 20 - Confirm Surveys Exported

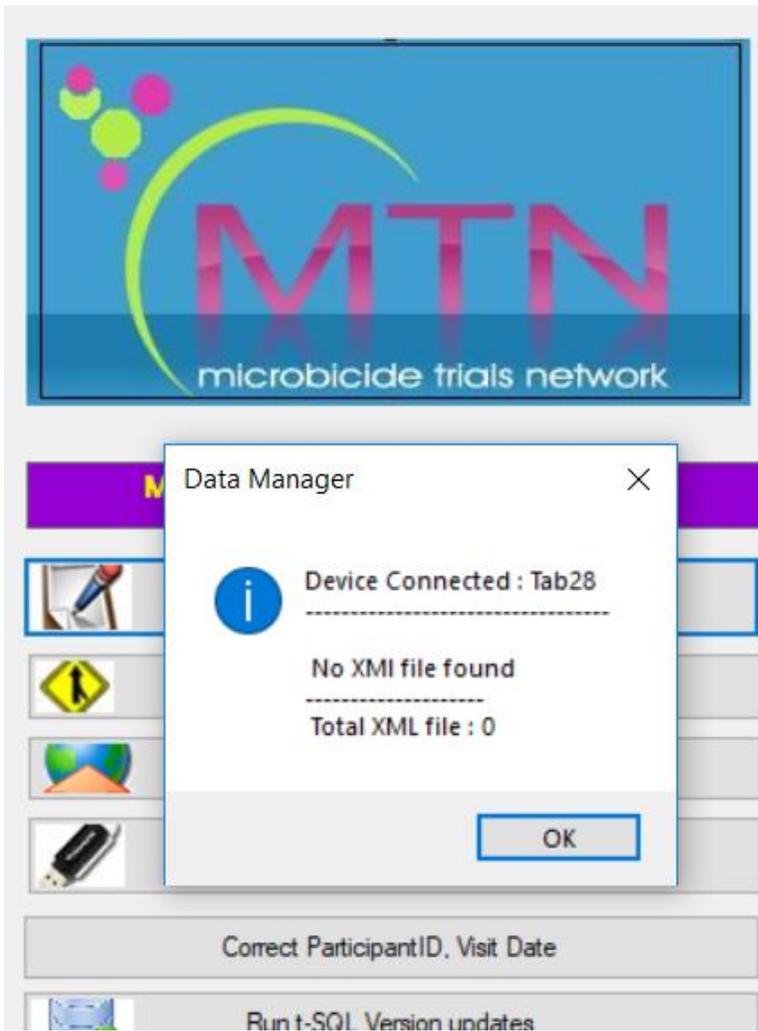


Figure 21- No XML File Found

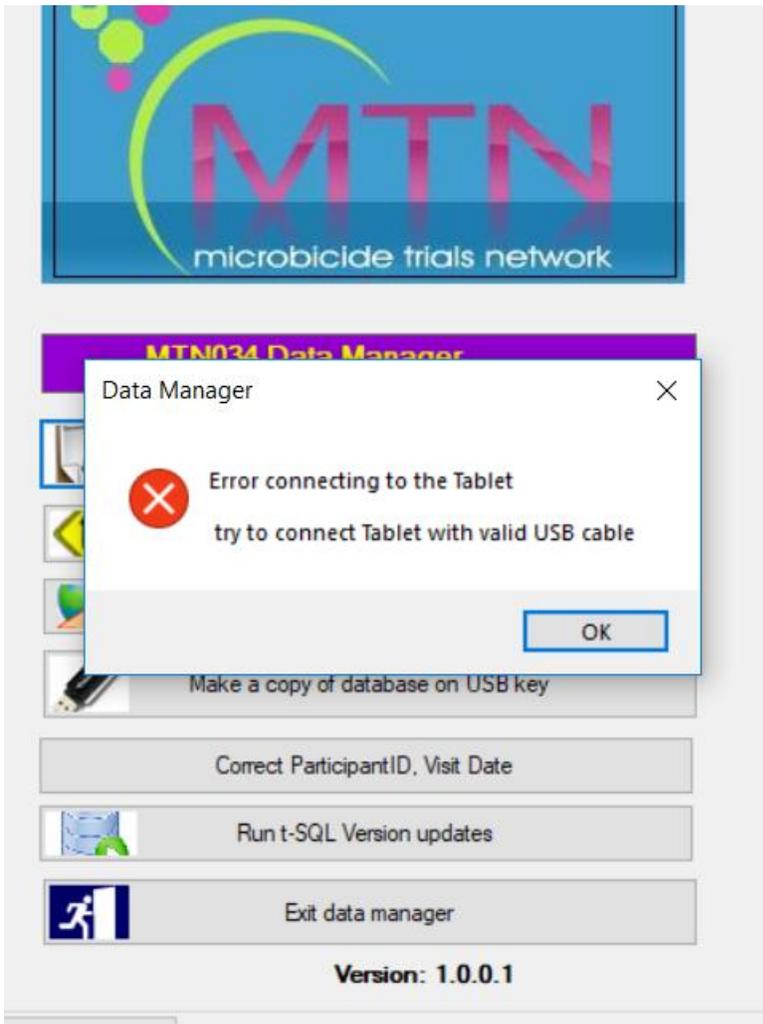


Figure 22 – Error Connecting to Tablet

Merging Exported Files on the Data Manager Laptop

1. After importing the files from the tablet, you will then merge them into the database on the laptop. Click **Merge imported XML file(s) to Database** (Figure 23).



Figure 23 – Merge Exported Files

2. After you merge the surveys, a pop-window will appear indicating how many surveys were successfully merged, as shown in Figure 24.

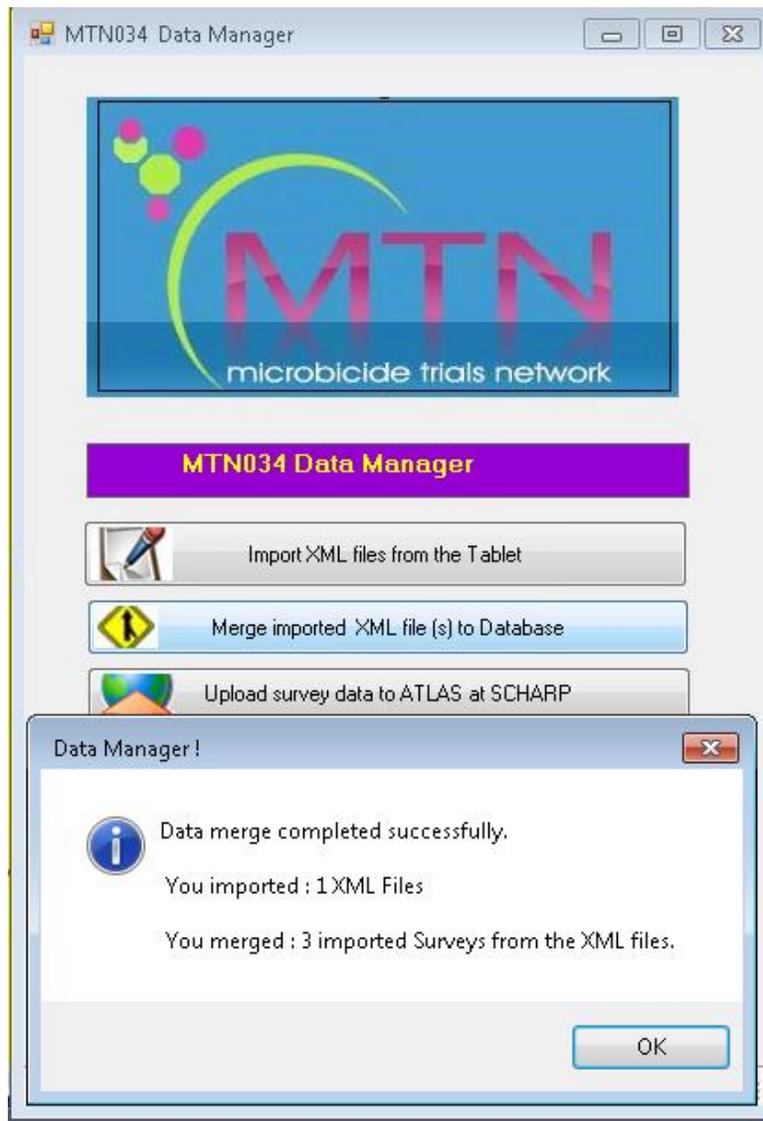


Figure 24 - Data Merged Successfully

Repeat the process of exporting the files from the tablet, importing the files to the data manager and merging the files into the database on the Data Manager laptop for each tablet.

Once all of the surveys from all of the tablets have been imported and merged in the Data Manager PC, the data will be uploaded to SCHARP.

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 tablets to the designated Data Manager laptop, the ACASI Data Manager will upload the ACASI database to the MTN Statistical Data Management Center (SDMC) at 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. Click on the third button in the Data Manager main admin screen, "Upload survey data to ATLAS at SCHARP" (Figure 19).
3. If the data preparation was successful, you will get a message that says, "done! OK" (Figure 26).
4. A folder will be created automatically with the current data and will be displayed after you click OK in the message display. The Folder will be created in: C:\ACASI\BACKUP\{MMDDYYYY} (Figure 27).

5. Surveys files will be automatically generated and grouped in an encrypted ZIP file inside the new created folder. The ZIP file name format: acasi_MTN034 -DDMMYYYY-HHMMSS-###.ZIP. Where DDMMYYYY is the day month and year, HHMMSS is the time in hours minutes and seconds, and ### is the Data Manager laptop name. For example: acasi_MTN034-10062017-193115-DataManagerPC1.ZIP (Figure 27).

The Encrypted ZIP file SHOULD NOT be RENAMED, OPENED or DELETED.



Figure 25 - Upload Data to SCHARP

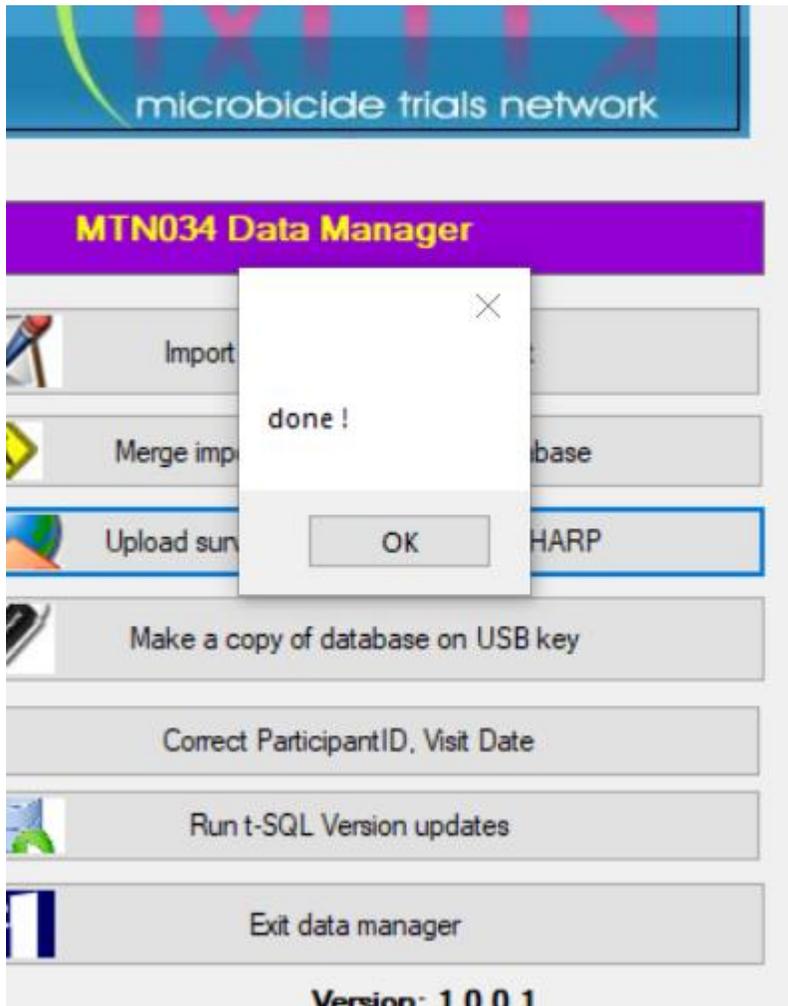


Figure 26 – Data Prepared Successfully

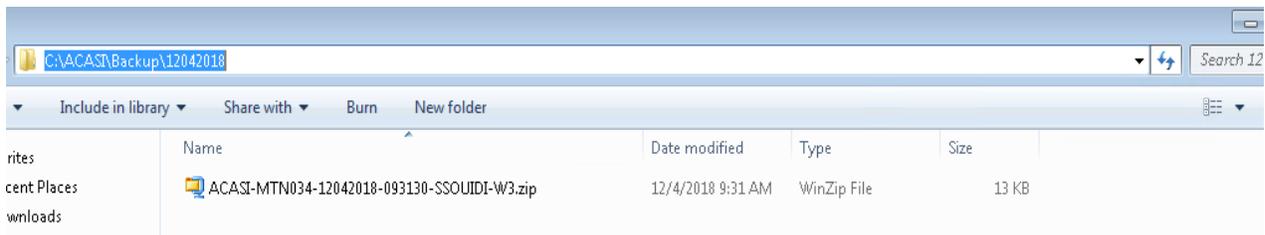


Figure 27 – Folder Automatically Created

6. A new SCHARP ATLAS web page will automatically open in Internet Explorer. Internet Explorer is the preferred web browser to connect to ATLAS website and upload the files.
 - a. If the Data Manager laptop is connected to the internet, you will see home page of the ATLAS web site.
 - b. If the internet is not available, you can connect to the ATLAS website at a later time and navigate to the SCHARP ATLAS website using Internet Explorer: Go to <http://atlas.scharp.org> .
7. Click on the **MTN** button on the front page (Figure 28).



Figure 28 - SCHARP Home Page

- a. You will be asked to agree to the terms of use by checking a box and then clicking the AGREE button (Figure 29).

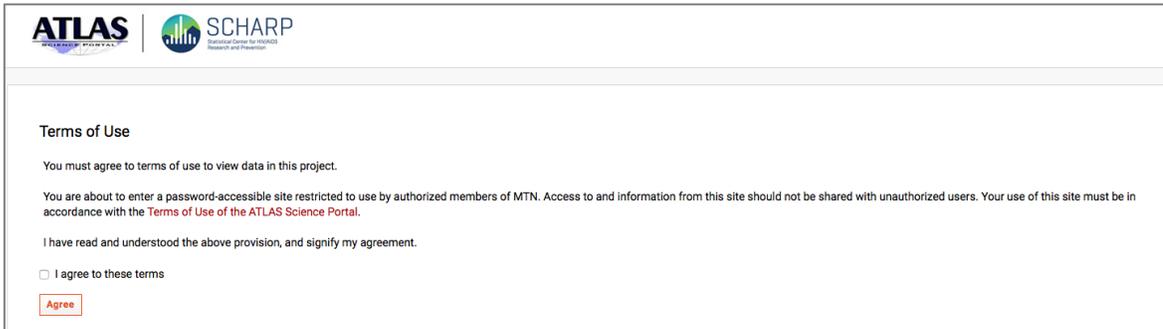


Figure 29 - SCHARP Terms of Use

b. Click on MTN 034 in the left hand navigation bar (Figure 30). You may need to scroll down to see 034.

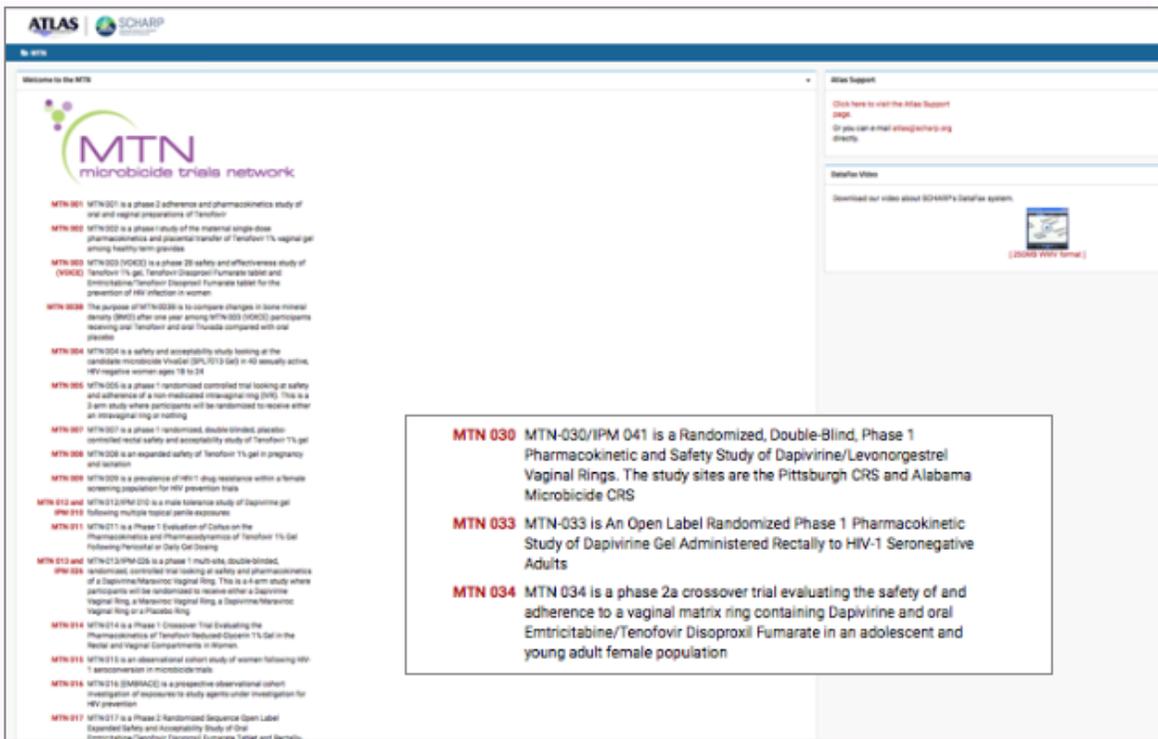


Figure 30 - Choose MTN034

c. At this point you will need to sign in to access the ACASI section of the website (towards the bottom, in the Secure Sections area).

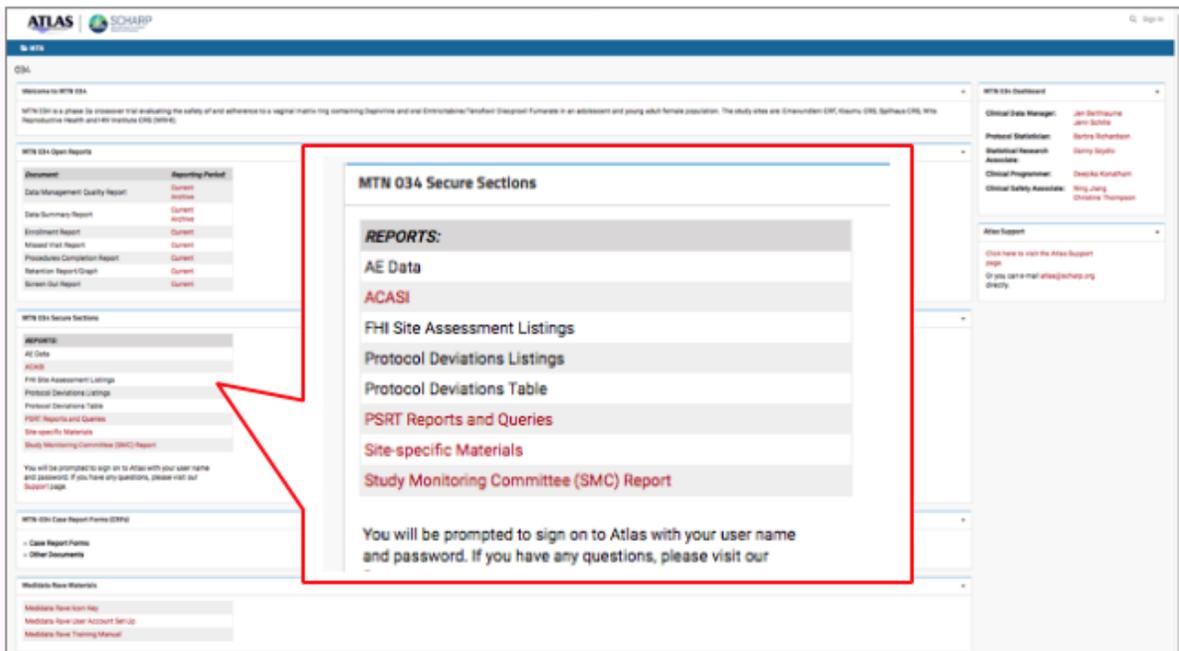


Figure 31 - MTN Secure Sections

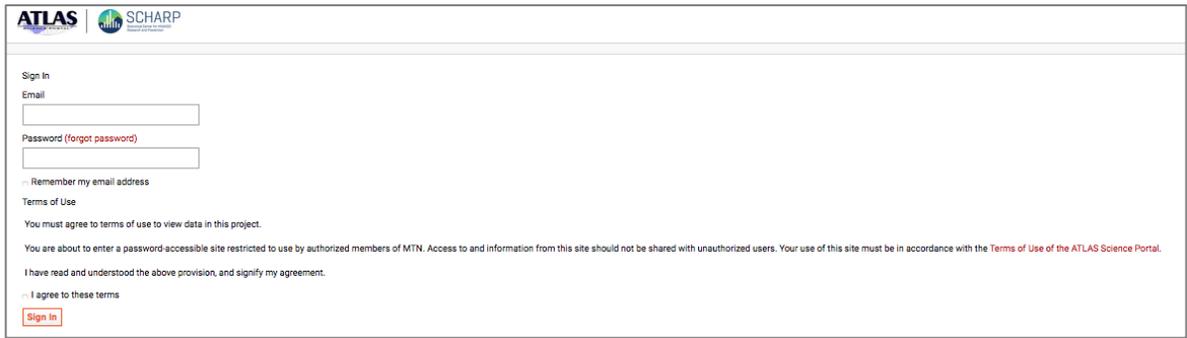


Figure 32 - SCHARP Login Screen

NOTE: Please be sure to not select other protocols that you may have access to for uploading ACASI data; for MTN-034 you should click on the 034 in the left dropdown navigation bar (Figures 31-32).

- d. Alternatively, you can browse directly to <https://atlas.scharp.org/cpas/Project/MTN/034/begin.view> and sign in with your Atlas email and password after agreeing to the Terms of Use. It may be helpful to bookmark this page in your web browser, so you can return to it easily.
- 8. Click the word **ACASI** on the navigation menu, and then click on the appropriate site.
- 9. Click the “Upload Files” icon on the lower portion of the page (Figure 33).

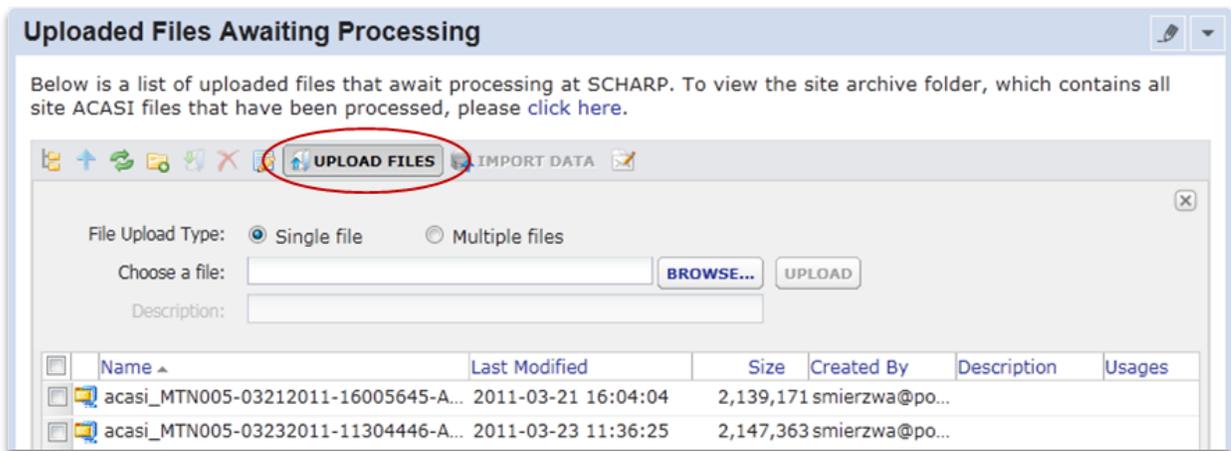


Figure 33 - Upload Data to SCHARP

- 10. Browse to the file to be uploaded on the data manager computer. *You will only need to upload the most recent file each day, as both new surveys and any changes will be added to that file cumulatively.*
- 11. Click the “Upload” button (Figure 33).
- 12. You should now see the file in the upload area (Figure 34). You may refer to this page to view a chronological list of recent uploads and confirm file upload. You can sort on any column, much like in Excel, by clicking the column header or the arrow to its right:

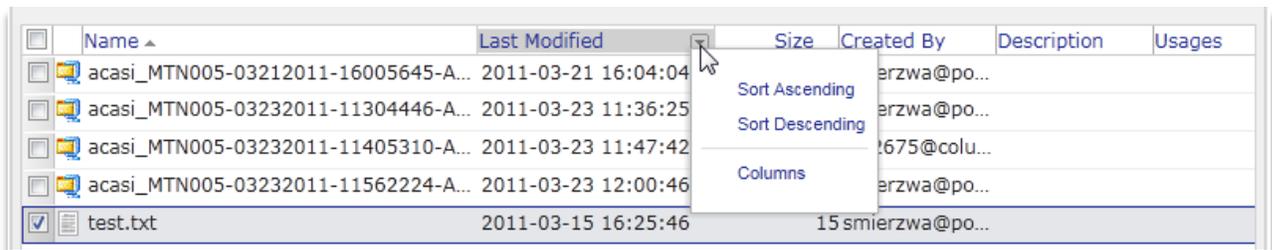


Figure 34 - Sort Data

Please Note: The file name is automatically generated by the App. Each file must be unique for each upload and the maximum upload size is 250MB. It is unlikely that files will reach this size, however, the Data Manager should check the size of the ZIP file before uploading to make sure it is no more than 250MB. The file size can be seen as shown in Figure 35.

For any support needs related to the data upload process, please send an e-mail to MTN034ACASI@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.



Figure 35 - Refresh List of Surveys

Backing up the ACASI Data

At the end of each workday on which at least one ACASI interview is administered, after transferring data from tablet to the Data Manager laptop and uploading the ACASI database to the MTN SDMC (i.e. SCHARP) via the ATLAS portal (as described above), the ACASI data manager will back up the ACASI database to the assigned portable data storage device (USB key). The USB backup key should be stored securely in a dry location, in a locked cabinet.

Creating folders on the USB key

1. The USB key needs to be structured with two folders, one within the other. The main folder is “MTN034_Backups.” Within the MTN034_Backups folder is a second folder “USBKey.” The first time the USB key is used, the Data Manager will need to CREATE the two folders on the USB Key. If the two folders are not created, it will not be possible to save the files from the Data Manager PC.
2. Once the folders have been set up on the USB Key, the database can be copied.
3. To copy the database onto the USB key, insert the USB key into the Data Manager laptop. In the Data Manager program, click the button, “Make a copy of the database on the USB key” (Figure 36).



Figure 36 – Make a Copy of Database on USB Key

4. If the database is copied successfully you will get a message that says: “USB KEY Backup completed!” (Figure 36)
5. If the USB key does not have these 2 folders (MTN034_Backups\USBKey), the backup won’t work, and you will get an error message that the USB KEY could not be found (Figure 37).
6. After the backup is completed successfully, click on “Eject Mass Storage” to safely eject the USB key from the Data Manger computer (Figure 38).

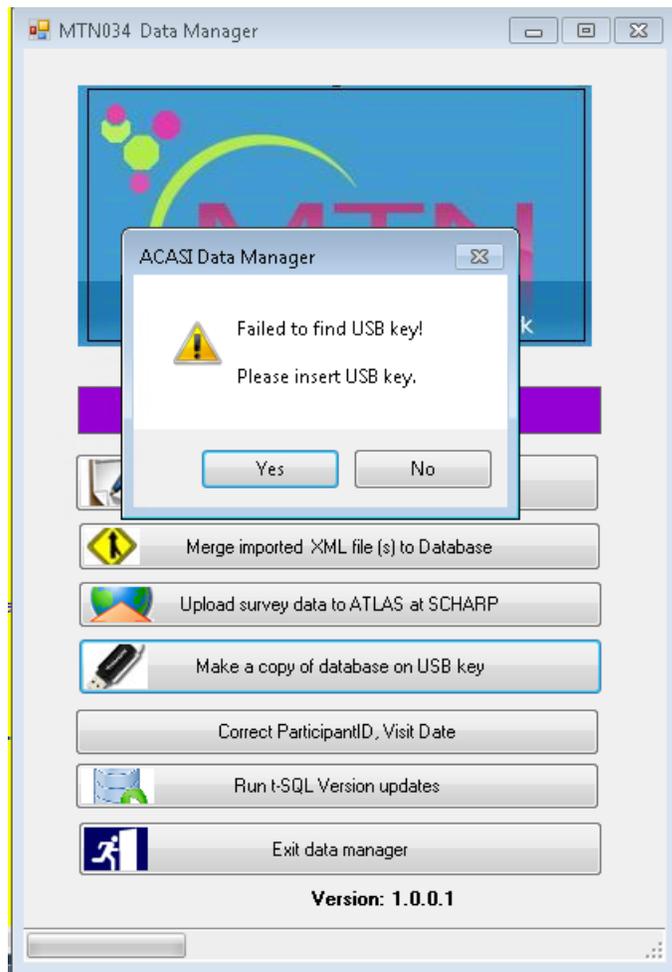


Figure 37 – Failed to Find USB Key

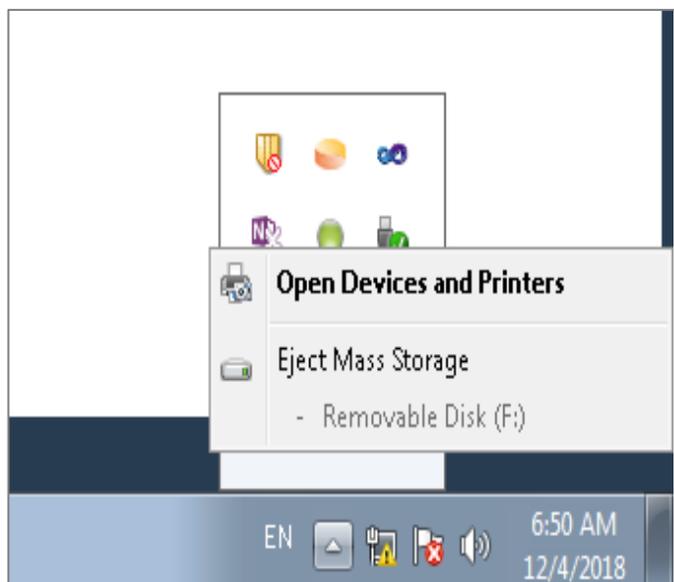


Figure 38 – Eject USB Key

12. CORRECTING KEY DATA IN THE ACASI DATABASE

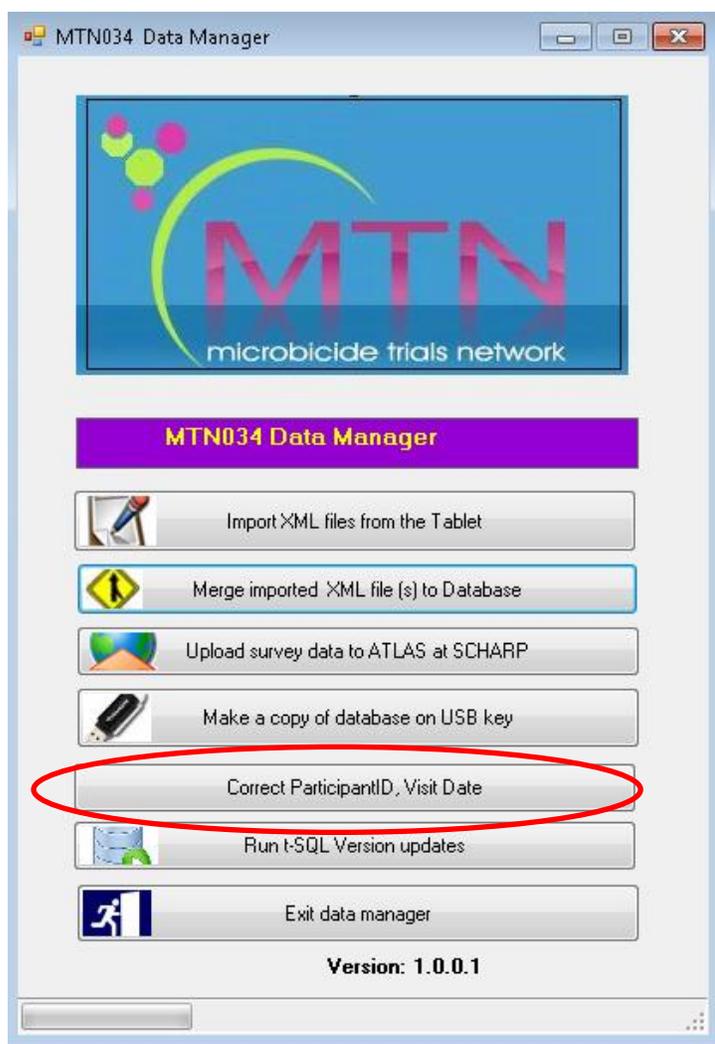


Figure 39 – Correct Key Data

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 is needed, the steps below will be followed:

The MTN SDMC will contact both the site and ACASI technical staff at the Population Council, Samir Souidi (ssouidi@popcouncil.org) and MTN034ACASI@mtnstophshiv.org.

1. The Data Manager at the site will log onto the ACASI laptop, using the assigned User Name and password.
2. From the Data Manager main administrative screen (Figure 40), click the button “Correct Participant ID, Visit Date.”
3. Enter User name and Password into the pop-up box when you click on “Correct Participant ID, Visit Date” (see Figure 40).

If you do not remember your User Name or Password, please contact ssouidi@popcouncil.org and MTN034ACASI@mtnstophshiv.org.

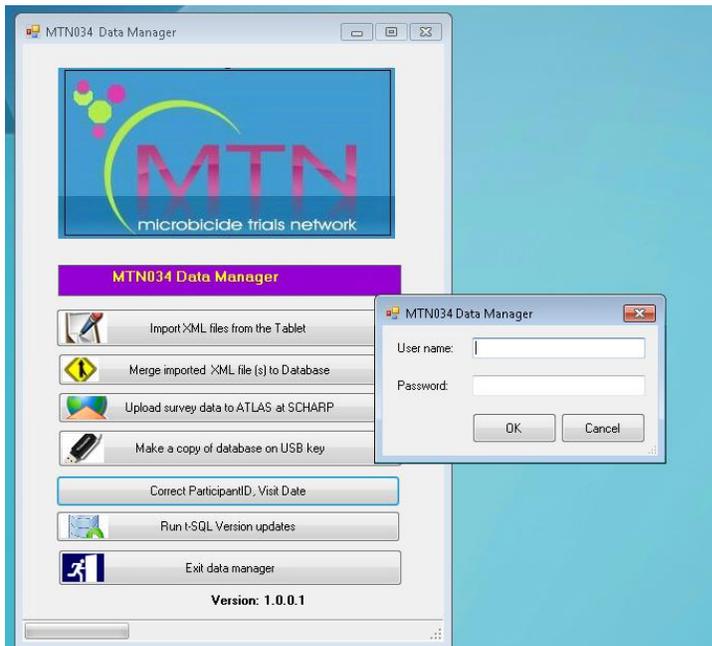


Figure 40 – User Name and Password to Correct Data

4. A search window will appear after a successful login (Figure 41).

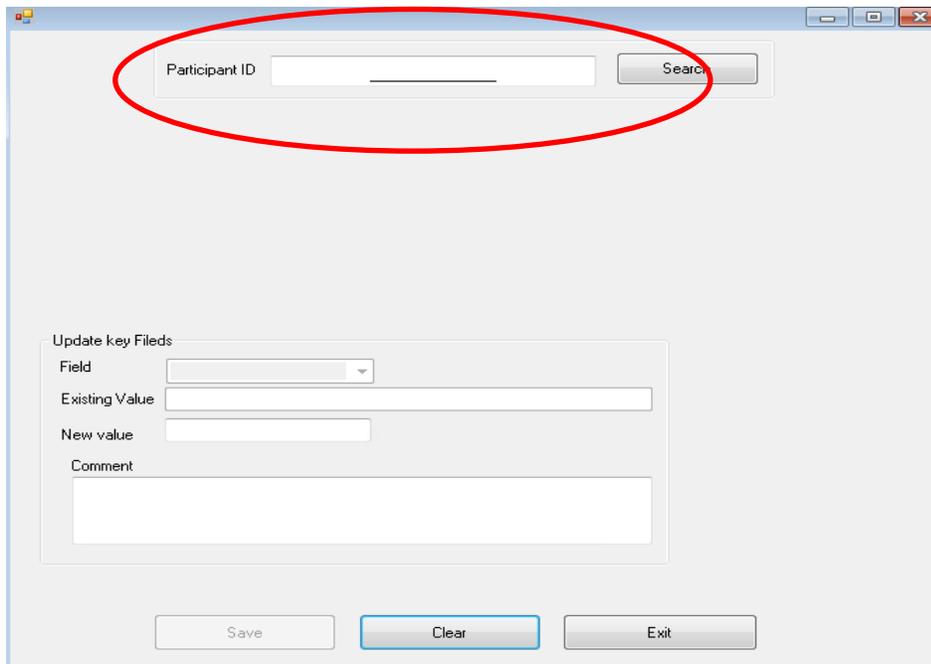
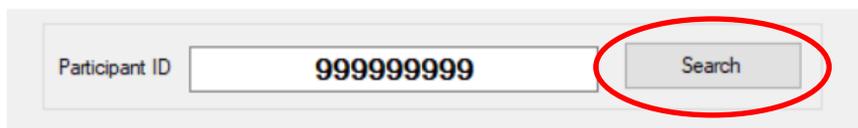


Figure 41 – Search Window to Correct Data

5. Enter the Participant ID number (PTID) at the top of the screen (enlarged below) and then click the Search button. The format for the PTID is #####, corresponding to the PTIDs for the MTN034 study.



6. If you do not use the correct PTID format, you will see this message:



7. After the PTID is correctly entered, you will see a list of questionnaires that have been done for the entered PTID. Based on the information provided to you from SCHARP (PTID, 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 (Figure 42).

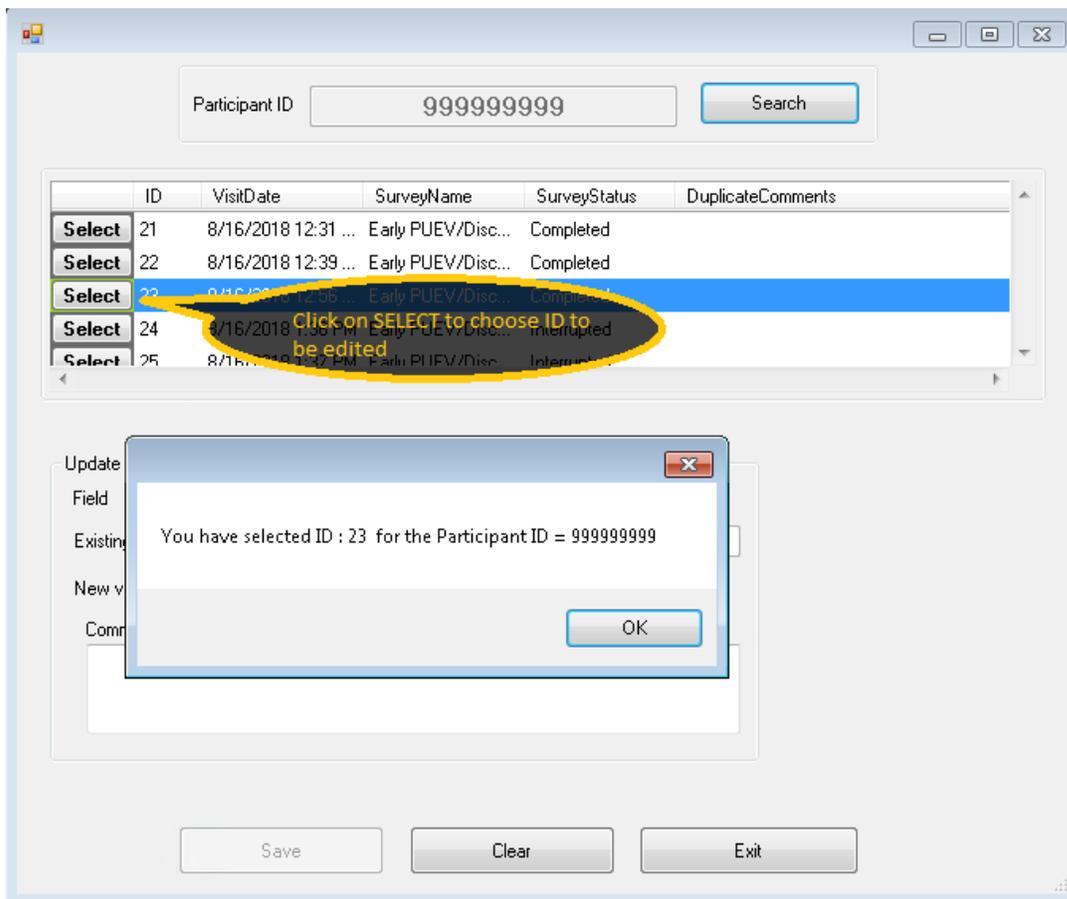
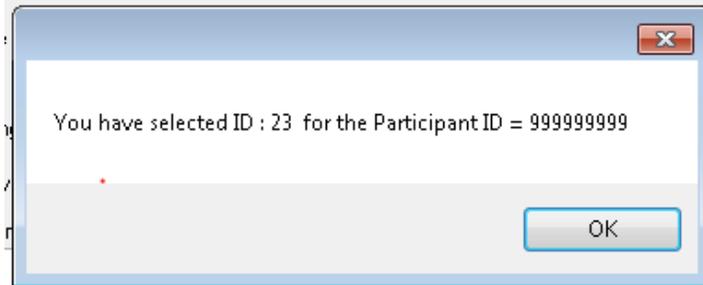


Figure 42 – Select Record

8. Once you choose a record by clicking **Select**, you will see the confirmation dialog box below.



9. Click the drop-down arrow to the right of the Field list (Figure 43) to choose which field you need to correct (Participant ID, Visit Date or Duplicate).

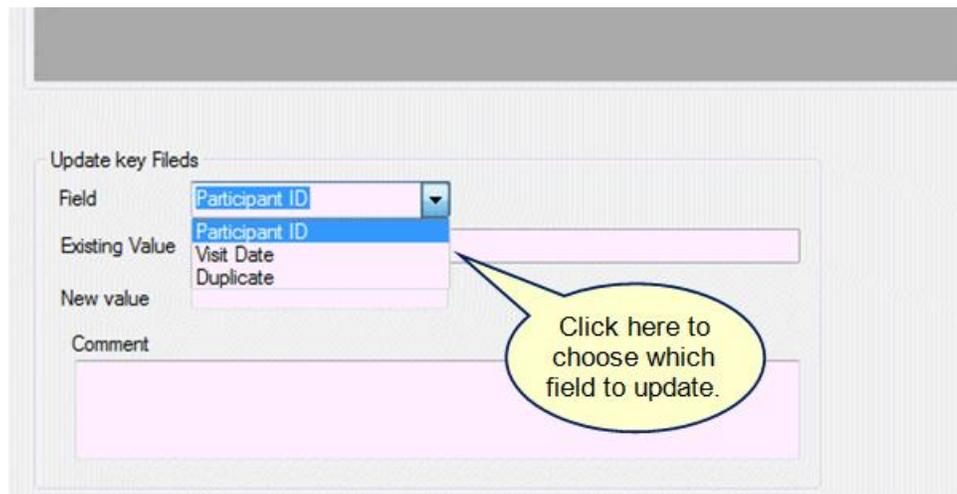


Figure 43 – Update Field

10. Press the Tab key on the computer keyboard to display the existing value.
11. Enter the new (correct) value in the “New value” field. If you are correcting the Participant ID or Visit Date, you must explain why the change is being made in the comment area.
12. Correcting Duplicate entry (Figure 44):
- If you are correcting a Duplicate entry, choose the reason for your change from the drop-down menu (next page, top Figure). If you choose “Other, specify”, you must enter your reason in the Comment box (next page, center Figure). If you do not enter a comment, you will see the error message at the bottom of this page.
 - Please follow these steps:
 - Select “Duplicate field” in the Field label
 - Select one of the reasons to justify the duplication:
 - Administered the wrong questionnaire
 - Administered a questionnaire at a visit when it was not required
 - Equipment or software malfunctioned
 - Restarted questionnaire after delay
 - Restarted questionnaire after participant terminated it
 - Other, specify

- If “Other specify” is selected, you must enter comments in the comment section. Comments must be in plain, unformatted text only. Do not use the Tab key, bullets, numbered lists, or any characters that are not alpha-numeric: &, %, \$, #, @, *, -, +, =, !, ~, ^, ☺, ☹.
- If you do not enter comments for “Other specify” you will get a message asking you to enter a reason for the change in the comments text box. You must enter a comment or the change will not be saved.

Participant ID

	ID	VisitDate	SurveyName	SurveyStatus	DuplicateComments
Select	3	1/23/2012 7:42 PM	Baseline	Interrupted	
Select	5	1/24/2012 8:28 PM	Baseline	Completed	
Select	6	1/24/2012 8:38 PM	Follow-up	Completed	

Update key Fileds

Field

Existing Value

Reason

Comment

Administered the wrong questionnaire
 Administered a questionnaire at a visit when it was not required
 Equipment or software malfunctioned
 Restarted questionnaire after delay
 Restarted questionnaire after participant terminated it
 Other, specify

Click here to choose the reason for your change.

Figure 44 – Correct Duplicate Entry

Update key Fileds

Field

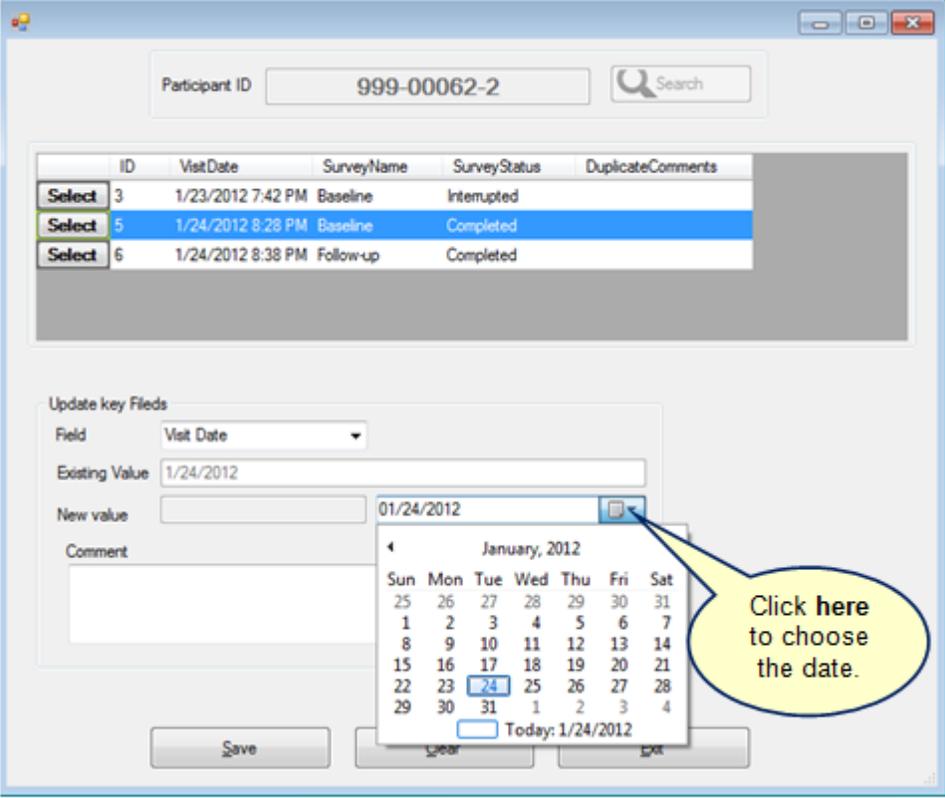
Existing Value

Reason

Comment

Please enter a reason for this change in the comment textbox.

13. If you choose to correct the Visit Date (Figure 45), 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.



Participant ID: 999-00062-2

	ID	VisitDate	SurveyName	SurveyStatus	DuplicateComments
Select	3	1/23/2012 7:42 PM	Baseline	Interrupted	
Select	5	1/24/2012 8:28 PM	Baseline	Completed	
Select	6	1/24/2012 8:38 PM	Follow-up	Completed	

Update key fields

Field: Visit Date

Existing Value: 1/24/2012

New value: 01/24/2012

Comment:

Save Clear Exit

January, 2012

Sun	Mon	Tue	Wed	Thu	Fri	Sat
25	26	27	28	29	30	31
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31	1	2	3	4

Today: 1/24/2012

Click here to choose the date.

Figure 45 – Correct Visit Date

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. The spreadsheet should be emailed to: MTN034ACASISupport@mtnstophshiv.org.

APPENDIX A: TRAINING SCRIPT FOR STUDY STAFF

Before the practice questions:

Introduction

- Explain that you are going to set up the tablet and show the participant how it works.
- Encourage them to stop you and ask questions at any time.
- Assure the participant that you will work together until she is comfortable using the tablet on her own.

Confidentiality

- Explain that all her answers to the questions will be kept confidential, meaning all her personal information will be kept private.
- Tell participant that at the end of the survey, she will be asked if she would like to speak to a counselor. Her response to that question will be seen by someone at the clinic, but none of her other responses can be seen.

During the practice questions:

Audio/Visual

- Explain that every question can be heard through the headphones.
- For literate participants: explain that the question is displayed on the screen also, so she can read along.
- For literate participants: describe how some screens require the participant to scroll through text (which is not shown in the practice questions)

Selecting a response

- Show the participant that responses are selected by touching the screen, and that the headphones are not “live” so she should not answer the questions out loud.
- When the participant is holding the tablet, ensure she knows not to touch the screen until she wants to answer (i.e. holds the sides only). Otherwise, she might accidentally select a response and the audio will stop.
- Explain that if she would like to answer before she has heard all responses, she can, but she should take time to think about the best answer to fit her situation.
- **Practice Question 1:** explain that many questions can be answered with a yes or no. Show her what an error message looks like by pressing the “no” option to the question “Are you a woman?” Demonstrate how to press the green button at the bottom of the page to go to the next question, and the white button to go back again.
- **Practice Question 2:** explain that some questions require a numerical response. Show the participant how to enter numbers and explain that when entering a double-digit number, she should pause between numbers if she needs to hear the number aloud. (E.g. When selecting 27, the audio will say “2” then “7.” If she enters the numbers too quickly, she might only hear “7.”) Show her the “clear” button that can be used if she enters the wrong number.
- **Practice Question 3:** explain that some questions will require her to pick out the correct category that applies to her. Note that if she enters the wrong category in this question, an error message will appear and ask her to amend her response.
- **Practice Question 4:** explain to the participant that she can deselect her response to questions that require one answer by pressing another response.
- **Practice Question 5:** explain that some questions are a follow-up to the previous question. Demonstrate how to go back to the previous page by pressing the white button at the bottom of the screen when necessary. *For Shona, this question is to demonstrate the need to scroll in longer

questions. Show the participant that the full question doesn't appear in the grey area on the top of the screen and that there will be cases where she will need to scroll to see the complete question by sliding her finger up while touching the question.

- **Practice Question 6:** explain that for questions that allow multiple responses (i.e. mark all that apply), the audio will stop when a response is selected. This means she will may have to listen to all options first or press the "repeat question" button after each selection, particularly if she cannot read. Show the participant how to deselect a response in the "mark all that apply" questions by touching it a second time.

Navigating survey

- Explain how to go to the next question by pressing "next" at the bottom of the screen.
- Explain how to have a question repeated by pressing the "Repeat Question" at the top of the screen.
- Explain how to go back to the previous question by pressing "previous" at the bottom of the screen. Let the participant know that she can only go back one question.
- Explain how to refuse to answer a question by selecting the star at the bottom of the screen

After practice questions:

Review important definitions

- Explain to the participant that she will be asked some questions about sex and the kind of sex she has.
- Review the definitions for vaginal sex, anal sex, primary sex partner, and any other term used in the survey that may be an issue based on the language the participant is taking the survey in.
- Remember that the terms used for these words may vary in different cultures and languages, so use the most appropriate terms for the local population when reviewing these definitions.
- At enrolment, Visit 9, Visit 16, and Visit 23, there is a question that will ask about "sex partners", followed by another question about "any other person" the participant has engaged in sexual activity with. If this is confusing, explain to the participant that the difference is that a "sex partner" is someone they are willingly in a sexual relationship with (e.g. boyfriends, casual partners, clients, etc.), whereas "any other person" refers to someone they are not willingly in a sexual relationship with.
- Ask the participant if she has any further questions before starting the survey on her own.
- Remind the participant that she will have privacy, but that you will be nearby in case she has any questions during the survey.
- Tell the participant to get you when she has finished the survey.

APPENDIX B: HARDWARE AND SOFTWARE RECORDING REQUIREMENTS

The following items are required to perform the required recordings for the MTN-034 REACH study:

1. Personal computer with following hardware qualities
2. Sound capability, either via integrated audio soundcard or integrated audio
 - One Microphone Port In (Audio In)
 - One Headphone Port Line Out (Audio Out)OR
 - USB port for both input and output
3. At least 100 MB of free hard disk space (for audio file storage)
4. Windows-based operating system, either Windows 7, 8 or 10
5. Audacity program
6. Personal computer (PC)-based headset with microphone with following qualities:
 - In-line and microphone volume control
 - Headphone frequency range of 20 Hz to 20 KHz
 - Microphone frequency range of 100 Hz to 10 KHz
 - Soft foam ear pads
7. 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

To ensure the best recordings:

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. If you will be recording the audio files in more than one session, make sure you use the same location and environment for all recording sessions.
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.

Also, please keep in mind:

- Underlined words are emphasized, but not strongly emphasized.
- Slight pauses follow commas.
- The recordings should be clear and understandable.
 - Reading of the questions while recording should be at a moderate pace.

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.

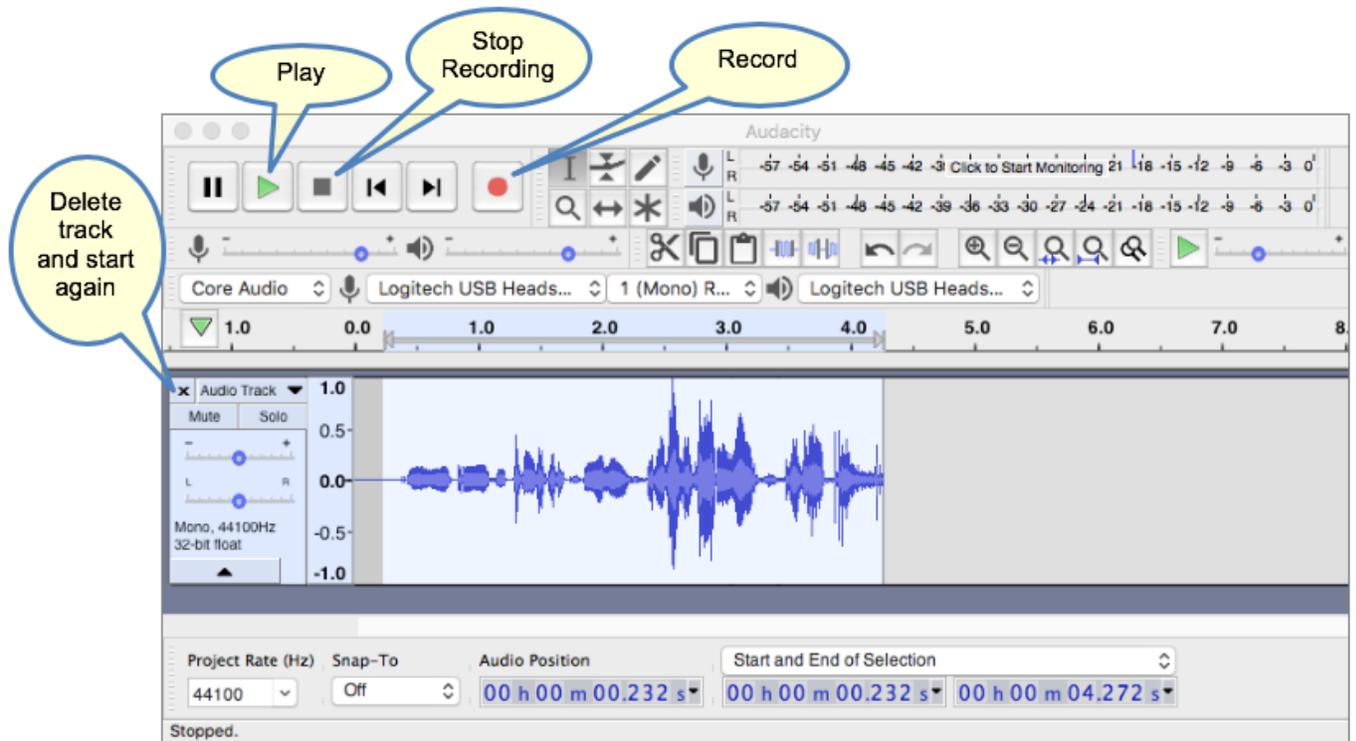


Figure 3 - Audacity Controls

5. Click the red circle button to start the recording and say "This is a test recording – 1- 2- 3 - "
6. Click the black square button to stop the recording.
 - To play back the recording, press the green arrow/triangle
 - Play the test recording several times to ensure the quality is good and there is no noise (such as static) at the beginning or the end of the recording.
 - If the sound quality is not adequate, try adjusting the volume on the headset itself and then play the test audio recording again.

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.
7. Go to the File menu and choose "Export As mp3" 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. You can accept the default formatting options shown in the Export dialog box.

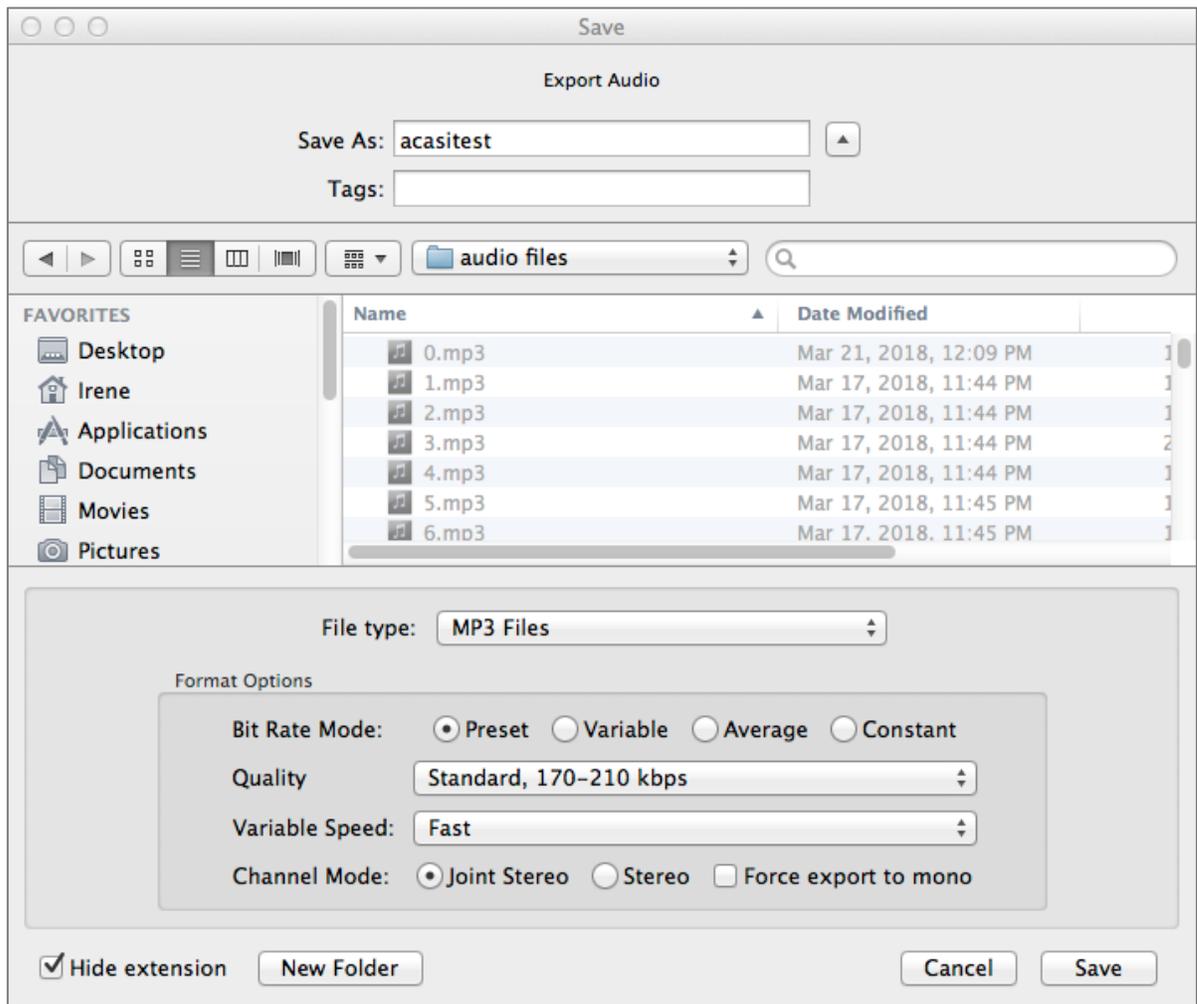


Figure 4 - Save Audio File

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 a folder on the desktop computer (e.g. audiophiles) and then uploaded to the folder for your language on this website: <https://app.box.com/folder/52765256959#>

Naming Conventions for Audio Files

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

1. question identifier
2. 3-letter language identifier
 - eng (English version)
 - lug (Luganda version)
 - Luo (Luo version)
 - Sho (Shona version)
 - Swa (Swahili version)
 - Xho (Xhosa version)
 - zul (Zulu version)

3. the “.mp3” extension

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

filename: intro1_eng.mp3 (English version)

intro1_lug.mp3 (Luo version)

intro1_sho.mp3 (Shona version)

Example: For Practice Questions

filename: PQ1_eng.mp3 (English version)

PQ1_luo.mp3 (Luganda version)

PQ1_swa.mp3 (Swahili version)

Example: For the Main Survey Questions

filename: B2_eng.mp3 (English version)

B2_xho.mp3 (Xhosa version)

B2_zul.mp3 (Zulu version)

APPENDIX C: SOP FOR RECOVERING LOST PIN

1. Each Tablet Admin will select a PIN for her tablet
2. She will write down the PIN on a piece of paper and seal it in an envelope
3. The envelope will be labeled with "PIN recovery for Tablet 1"
4. The site Data Manager will retain the PIN recovery envelopes for all 3 tablets
5. In the event that the Tablet Administrator forgets her PIN, or if something happens to the Tablet Administrator (i.e. she leaves the site unexpectedly), the envelope will be opened so that the PIN can be retrieved.
6. Once the PIN is retrieved, it will need to be changed.

NOTE: Before the PIN is changed, the Data Manager will need to upload any data that has not yet been exported from the tablet to the Data Manager laptop. Once the latest data has been transferred to the Data Manager (merging XML file), the PIN needs to be changed. The documentation procedure will follow steps 1-4 again for the new PIN.