

Section 16. Behavioral Measures

This section of the SSP contains information about the necessary preparation, equipment and process for participant completion of the web-based behavioral assessments and the semi-structured interview. The behavioral assessments of the MTN-013/IPM 026 protocol will be collected via: 1) Web-based Computer Assisted Self-Interview (CASI) questionnaires; and 2) An interviewer-administered Semi-Structured Interview (SSI).

16.1 Overview

Behavioral assessments will be captured through web-based Computer Assisted Self-Interview (CASI) questionnaires and an interviewer-administered semi-structured Interview (SSI). CASI computer interviews and SSI form are source documentation and must be maintained in accordance with the guidelines for other study documentation. Table 1 outlines the timing (by study visit) and mode (by instrument) each behavioral assessment should be completed.

Table 1 – Behavioral Assessments: Timing and Mode of Administration

Instrument Name	Timing	Mode of Administration
Baseline Questionnaire	Day 0 (Enrollment)	CASI
Ring Adherence Questionnaire	Day 7, 14, 21, 28 Early product discontinuation*	CASI
Protocol Adherence Questionnaire	Day 7, 14, 21, 28 Day 31, 35, or 42 (based on random assignment) Day 52/Early Termination	CASI
Acceptability Questionnaire	Day 28 & 52/Early Termination**	CASI
Semi-Structured Interview (SSI)	Day 28	Interviewer-administered

*If prior to day 28; ** if not previously completed

16.1.1. Troubleshooting

For any problems with the computerized (CASI) questionnaires, either accessing them or completing them, or with the CASI study computer, please notify the team immediately by sending an email to the alias list mtn013casi@mtnstopshiv.org. For any problems with the WORD template and electronically entering data for the SSI or sending files to RTI, or queries about text editing and revisions, please notify the RTI team immediately by sending an email to mtn013@rti.org (see Appendix 16-2 “MTN013 SSI Step-by-Step Site Instructions”).

A group of staff members will be available to assist and troubleshoot any problems with the behavioral assessments. They include the following:

RTI International: Helen Cheng and Ariane van der Straten
SCHARP: Missy Cianciola and Lynda McVarish
FHI: Sherri Johnson and Stephanie Horn

16.2 Equipment Requirements and Set-up

The operations manual of the PC or laptop used for the CASI study computer should be consulted for hardware and software specifications, and instructions on how to use the computer (i.e., turning a computer on and off, etc.). Other questions should be directed to the MTN-013 CASI Instrument Troubleshooting email alias.

Each study site must have a desktop or laptop computer connected to the internet that is for use by the MTN-013 study participants. Select a location for the CASI study computer that is private (i.e. the screen should be out of sight of staff members, but allows study staff to be nearby to answer questions or assess whether the participant is having technical problems. Also, the location should be out of sight and of hearing of other participants while answers are being entered. The location must have an electrical outlet and a jack for broadband connection, unless a reliable wireless connection is used. The CASI study computer should be plugged into an AC power source. An external mouse should be connected to the computer. Each site is responsible for addressing issues of security, privacy, background noise, lighting, ergonomics, and overall participant comfort in its site specific procedures. Staff members should be familiar with the use of the computer and the content of questionnaires, in case participants raise any questions.

16.2.1 Keyboard and Mouse Use

The CASI study computer will require a keyboard and an external mouse. To use the mouse, the following instructions are provided:

- Move the cursor, move mouse.
- To select an object, tap left button once. To unselect an object, tap left button again once.
- References in this SSP to ‘clicking’ on icons or other items displayed on the screen are meant to direct the user to press the left button.

16.3 Data Collection Instruments

16.3.1 Baseline Questionnaire

The Baseline Questionnaire will be administered at the Enrollment Visit. A staff member will access the following web page for the CASI Baseline Questionnaire: www.ssharp.org/MTN013Baseline. The staff member will select the participant’s ID (PTID) to log in.

The staff member should provide instructions to participants for using both the keyboard and mouse, as well as moving from page to page to answer questions using the ‘NEXT’ and ‘PREVIOUS’ buttons (not the browser arrows). Initially, the participant will be presented with simple practice questions (e.g., “choose all that apply,” “select one response”). The staff member should verify participant's comfort with using the mouse and keyboard, and navigating through the questionnaire. The participant should be given time to complete the practice questions, with assistance as needed. Staff should ensure that participants understand how to answer questions by ticking boxes or entering numbers, and how to change invalid entries. Invalid entries are those that are not accepted by the program, either because they contradict information that the participant previously entered or because they are not permitted (e.g., numbers that are out of the possible range). Staff should inform the participant that she can refuse to answer any question by ticking the “**refuse to answer**” button in the bottom corner of the screen. If the participant is unsure of her answer, she should be encouraged to make her best guess rather than to refuse. Participants should be informed that they may go back and change answers at any time, using the back

arrow. Staff should then remind participants that they are available to answer any questions or assist with administration of the computer.

Once the practice questions have been successfully completed, the staff member will re-enter the participant's ID (PTID) and select the visit code and date.

Following this, the participant should be left alone to complete the Baseline Questionnaire. This questionnaire will measure study participant's background characteristics, assess her initial attitude towards the vaginal ring, her history of sexual behavior and use of vaginal products. At the end of the questionnaire, a message will appear instructing the participant to click 'NEXT' if she wants to save her answers. The final screen will indicate to the participant that she has completed the questionnaire and that she should communicate this to the staff member.

16.3.2 Ring Adherence Questionnaire

During the ring-in phase, at Day 7, 14, 21, 28, or at early product discontinuation, the participant will complete a Ring Adherence Questionnaire using a Web-based questionnaire and following procedures similar to those utilized for the Baseline Questionnaire. At the appropriate time, a staff member will access the Web page for the Ring Adherence Questionnaire: www.ssharp.org/MTN013RingAdherence. The staff member will then double enter the PTID, followed by visit code and date. Additionally, the date of the last computer interview will be double entered. Next, the participant will be left to answer the questionnaire on her own.

The Ring Adherence Questionnaire will explore the experiences the participant had using the ring since the previous CASI questionnaire. The participant will answer questions about inserting and removing the ring. She will also discuss her experience with both voluntary and involuntary expulsion of the ring and subsequent reinsertion. At the end of the questionnaire (penultimate screen), a message will appear instructing the participant to click 'NEXT' if she wants to save her answers. The final screen will indicate to the participant that she has completed the questionnaire and that she should communicate this to the staff member.

16.3.3 Protocol Adherence Questionnaire

During the ring-in phase at Day 7, 14, 21, 28, and during the ring-out phase at days 31, 35, or 42 (based on the participants randomization), and 52/early termination, the participant will complete a Protocol Adherence Questionnaire using a Web-based questionnaire and following procedures similar to those utilized for the Baseline Questionnaire. At the appropriate time, a staff member will access the Web page for the Protocol Adherence Questionnaire: www.ssharp.org/MTN013ProtocolAdherence. The staff member will then double enter the PTID, followed by visit code, and the date. Additionally, the date of the last computer interview will be double entered. Next, the participant will be left to answer the questionnaire on her own.

The Protocol Adherence Questionnaire will explore a participant's sexual behavior and her use of vaginal products since last CASI questionnaire. At the end of the questionnaire (penultimate screen), a message will appear instructing the participant to click 'NEXT' if she wants to save her answers. The final screen will indicate to the participant that she has completed the questionnaire and that she should communicate this to the staff member.

16.3.4 Acceptability Questionnaire

At Day 28 or at early termination (if not completed before), the participant will complete an Acceptability Questionnaire using a Web-based questionnaire and following procedures similar to those utilized for the Baseline Questionnaire. At the appropriate time, a staff member will access the Web page for the Acceptability Questionnaire: www.ssharp.org/MTN013Acceptability. The staff member will then double enter the participant's ID, followed by visit code and the date. Next, the participant will be left to answer the questionnaire on her own.

The Acceptability Questionnaire will investigate a participant's general experience with the ring, her likes and dislikes, problems with and concerns about the ring as well as her willingness and likelihood of using the ring in the future. At the end of the questionnaire (penultimate screen), a message will appear instructing the participant to click 'NEXT' if she wants to save her answers. The final screen will indicate to the participant that she has completed the questionnaire and that she should communicate this to the staff member.

16.3.5 Semi-Structured Interview

Immediately following the Acceptability Questionnaire at Day 28 or early termination, a staff member will administer the SSI Questionnaire (using the hard copy form to record the participant's response). This questionnaire will explore, through open-ended questions, the participant's overall experiences and feelings using the ring during the trial, including any physical, mental or emotional concerns or experiences she encountered; her experiences using the ring and opinions about using it continuously for a month; her likes and dislikes; and her recommendations for future changes to the ring.

The staff member should explain that a few additional questions are being asked in person to more thoroughly explore the participant's feelings, and that her responses will be entered into the computer after her visit. The interviewer should endeavor to record open-ended responses verbatim, as provided by the participant. However, the essence and key points may be summarized by the interviewer for lengthy responses.

Note: When writing and entering these data, direct quotations from the participant should be indicated with quotation marks to distinguish them from interviewer summaries.

The interviewer should probe to get more specific and detailed information in response to each question, and may write responses on the reverse side of the form, in the margins, or on additional sheets of paper if needed. For example, if a participant reports that use of the ring was "difficult," probe to better understand what she means by difficult (i.e. painful, interfering with daily life, physically hard, etc.). The participant may spontaneously raise comments or questions during the interview that are unrelated or not a response to the questions being asked. It is allowable, but not required, to probe on and record data regarding these issues. At the end of the questionnaire, the study staff member should quickly review the form for completeness, clarify with her any unclear parts or gaps in his/her notes; thank the participant, and escort her to the next stage of her visit. Then the interviewer can expand further his/her notes (on the same day) to ensure completeness of the information. The "comments" section at the end of the form can be used by the interviewer to summarize how the SSI went, including the mood or affect of the participant during the interview

16.3.5.1 Semi-Structured Interview Data Entry

Semi-structured interviews conducted prior to and on April 2, 2012 will be entered into SSI Questionnaire on the web-based CASI system. SSI conducted on and after April 3, 2012 will be entered using the electronic (MS Word) SSI template and uploaded to the FTP server directory.

Participant responses to the Semi-Structure Interview questionnaire (including the “comments” section) should be entered using the electronic (MS Word) SSI template on the same day the interview is administered and by the interviewer him/herself. The staff member should create a separate SSI Word file for each PTID per instruction in Appendix 16-2: MTN013_SSI_site instructions.

The PTID will be entered, followed by the visit code, the date on which the interview was performed and the initials of the interviewer. The visit code is already entered in the SSI Word template and will remain the same for each participant (10.0). The data entry staff member will write the date of data entry and his/her initials on the SSI paper form and enter those values into the PTID-specific SSI Word file as well. Participant responses should then be entered into the SSI Word file under each respective question.

NOTE: ALL responses should only be entered into the GRAY fields of the PTID-specific Word file. No information should be entered in the file outside of these gray fields.

All open-ended textual responses should be entered verbatim in sentence case, meaning not using capital letters. All direct quotations from participants should be written using quotation marks. If a participant does not respond to a certain question, staff should type, ‘Did not answer’ in the response box. Site staff should review and ensure proper grammar usage before the entry of SSI questionnaire date is considered complete. Following data entry, the staff member should write “entered” on the SSI paper form and file the document in the participant file.

Once the SSI Word file is complete, the file should be uploaded to the site’s respective folder on the RTI FTP server directory. To access the FTP server, staff must download and install the FTP client, FileZilla. See Appendix 16-2 for installation instructions.

Note: Hand written notes on the SSI paper form (source) do not have to match the text in the SSI Word file (i.e., if the answer to one question is written on the form under the heading of a different question, because of the conversational nature of the SSI, that is acceptable.)

If any participant discontinues study participation early, or has a modified Day 28 Visit, she will NOT be required to complete the SSI Questionnaire at the time of her study discontinuation.

16.3.5.2 FTP Installation and use

FTP use is account, username and password protected with only designated team members from RTI and the site given access, to ensure data safety and confidentiality. The encrypted FTP site tracks user activity and file uploads making it easy to manage precisely by whom and when new files are updated, what changes are made, and what versions are most current. See Appendix 16-2 for detailed step by step instruction of the FTP installation and instructions to upload and download the electronic SSI Word files.

16.3.5.3 Managing Data and Data Quality Control

Once an SSI Word file has been created for a participant, that file is uploaded to the following folder on the FTP site: “//*MTN013 SSI/Site X/Original Files.*”¹ Each site will have its own designated file directory on the FTP server. Site staff will send the RTI team an email each time a new SSI Word file is added to the FTP site for review.

Site staff will maintain a log of the completed SSI Word files in the Excel document template provided to the site by RTI. This log should be updated regularly and uploaded to the FTP server directory. File logs will be stored in the “//*MTN013 SSI/Site X/File Log*” directory.

Once quantitative data is transferred to the FTP site, RTI performs additional cleaning checks for spelling and grammatical errors. Data is not edited for content but only for spelling and grammatical corrections. Queried documents will be renamed by RTI (see below for details) and uploaded to the FTP server in a folder designated for reviewed files, “//*MTN013 SSI/Site X/Queried Files from RTI.*”

Site staff will download the queried file(s) from the FTP server (see Appendix 16-2 for detailed step by step instructions) to review the requested changes and comments, communicate with the RTI team about any questions or concerns. Site staff will make the corrections to the file(s) as needed and update the file name (see below for details). Data is then transmitted back to RTI via the FTP server in the following folder: “//*MTN013 SSI/Site X/Query Responses from Site X.*”

The RTI team will review the corrected file(s). Once the file is considered final, the RTI team will create a final file and upload it to the FTP server to “//*MTN013 SSI/Site X/Final Files.*”

Notes on filenames: Each time a document is edited, the editor should add their initials to the filename without changing any other part of the filename. The first time the file is named there is no need to include the editor’s initials. It is only upon subsequent editing (cleaning) that this occurs. For example, when edited for the first time, “*MTN013_SSI_1001.doc*” would become “*MTN013_SSI_1001_CM.doc*,” and “*MTN013_SSI_1001_CM_NM.doc*” for the second revision. Once the document is finalized, all initials should be removed from the name and replaced with the word “FINAL,” as in “*MTN013_SSI_1001_FINAL.doc*”

16.3.6 Question-by-Question Instructions

A question-by-question guide, that explains the purpose and intention of each question, has been developed as reference for the CASI questionnaires and the SSI. These guides are available on the MTN-013/IPM 026 webpage under the Study Implementation section. Staff should become familiar with the question-by-question guides, and ensure that they are reviewed prior to the enrollment of the first participant. The guides should be consulted if participants request assistance in the interpretation of a CASI question, or if staff members are unclear with the meaning of a CASI question.

¹ “Site X” is a generic placeholder name for the specific site name. Each site will have its own directory listed under its name in which its files will be stored.

16.4 Special cases and Technical issues

16.4.1 Hard Copy Back-up

Hard copy versions of CASI questionnaires will **not** be distributed in this study. In the event of technical problems (i.e. server or power outage) that would preclude a participant's ability to complete the questionnaire online, participants may complete the appropriate questionnaire at a later time or date, when the system is functioning, as long as it is within the visit window. Otherwise, these data will be considered missed. These unique circumstances should be documented in the chart notes and a brief description recorded on the Follow-up CASI Tracking CRF.

SSI questionnaires will be available in hard copy for note taking by the interviewer. For any technical problems accessing or using the Word template for the SSI or the FTP site, contact the MTN-013 RTI team at mtn013@rti.org.

16.4.2 Split or interrupted visits

Site staff should ensure that all CASI questionnaires are always completed on the same date as the PK specimen collection. However, should a problem occur that prevent this from happening, the CASI questionnaires may be completed on a different date as long as the date is within the visit window. These unique circumstances should be documented in the chart notes and a brief description recorded on the Follow-up CASI Tracking CRF.

All CASI data from a given questionnaire must be collected on the same day. If a participant needs to briefly interrupt her computer session (i.e. attend to a call, go to the bathroom), at the discretion of the site staff, she can do so, and resume the CASI where she left it, as long as the survey window remains open. If the participant requires a longer interruption, or needs to leave the clinic, resulting in a split visit, she must close the interview window and will need to complete that CASI questionnaire in its entirety at her next visit. If duplicate CASI questionnaires are present for the same PTID and date, the fully-completed CASI questionnaire will be the one used in study analyses. These unique circumstances should be documented in the chart notes and a brief description recorded on the Follow-up CASI Tracking CRF.

16.4.3 Management of errors on CASI

Once a CASI questionnaire is completed, no one can change the responses or administrative fields, including site staff. If errors are noted by site staff for the administrative section (or by participants to the site staff on the questionnaire section), notify the mtn013casi@mtncshiv.org.

To facilitate the troubleshooting process, please indicate in your email a description of the problem, including a copy of the error message(s), if any, and date and time of when the problem occurred. The CASI troubleshooting team will assess the problem and communicate with site staff about resolutions. If this occurs, you should document it by keeping a record in the participant's file. A record will also be made in the MTN-013 weblog.

16.5 Staff Training

Site staff that will be assisting participants with CASI or administering the SSI is required to complete at least 2 practice sessions for each instrument.

For testing please access questionnaires through the websites indicated above. The following test PTIDs should be used:

PITT TEST PTIDs		UAB TEST PTIDs		Fenway TEST PTIDs
999-60001-3		999-60011-7		999-60021-9
999-60002-4		999-60012-8		999-60022-5
999-60003-8		999-60013-4		999-60023-2
999-60004-6		999-60014-2		999-60024-0
999-60005-2		999-60015-6		999-60025-8
999-60006-0		999-60016-9		999-60026-6
999-60007-1		999-60017-5		999-60027-7
999-60008-7		999-60018-3		999-60028-1
999-60009-5		999-60019-1		999-60029-4
999-60010-0		999-60020-3		999-60030-5

Upon completion of testing at each given site, an email should be sent to the MTN 013 CASI alias list: mtn013casi@mtnstopshiv.org indicating the number and type of tests completed, name of staff members completing test questionnaires, and a description of any problems encountered.

Section Appendix 16-1
QUICK TIPS FOR WEB-BASED BEHAVIORAL ASSESSMENTS

- Prior to starting a questionnaire, make sure that the computer, internet connection, keyboard and mouse are connected and working properly.
- Make sure that the participant is comfortable and has privacy to assure the confidentiality of her responses.
- Start the questionnaire by typing the Web address to the corresponding Behavioral Assessment:
 - Baseline Questionnaire (Enrollment Visit) www.ssharp.org/MTN013Baseline
 - Ring Adherence Questionnaire (Day 7, 14, 21, 28, early product discontinuation (†)): www.ssharp.org/MTN013RingAdherence. [† if prior to day 28]
 - Protocol Adherence Questionnaire (Day 7, 14, 21, 28, 31/35/42 & 52/ET): www.ssharp.org/MTN013ProtocolAdherence.
 - Acceptability Questionnaire (Day 28 & 52/ET*): www.ssharp.org/MTN013Acceptability. (* if not completed previously)
- Make sure that the participant is comfortable with using the mouse and keyboard.
- Confirm that it is the correct questionnaire.
- Enter participant's ID to enter the questionnaire.
- Allow participant to complete the practice questions (Baseline questionnaire only).
- Assist the participant as needed (Baseline questionnaire only).
- **For the four CASI questionnaires**, enter or select: participant's ID, visit code, and date. Additionally, enter the date of the last computer interview on the Ring Adherence Questionnaire and on the Protocol Adherence Questionnaire.
- Confirm that all values entered by staff are correct.
- Instruct the participant that when she reaches the end of the survey, she will see a screen that says "Thank you for completing this questionnaire!" The participant is not finished until she reaches this end screen and click on the NEXT button. At that point the participant should leave the computer as it is and notify a staff member.
- If a participant is interrupted and does not complete a CASI questionnaire in one sitting, based on site staff judgment and length of interruption, she can complete the CASI questionnaire later as long as it is **on the same day**. However if the computer window has been closed before the CASI was completed, or if there is a split visit and the participant cannot complete the CASI that same day, she will need to start a NEW CASI survey from the beginning.
- **For the SSI**, record participant responses on a hard copy of the SSI form. Enter field notes into the electronic MS Word template for the SSI as instructed in Appendix 16-2.

Appendix 16-2
MTN013 SSI STEP-BY-STEP SITE INSTRUCTIONS

A. Introduction

Immediately following the Acceptability Questionnaire at Day 28 or early termination, a staff member will administer the SSI Questionnaire (using the hard copy form to record the participant's response). This questionnaire explores, through open-ended questions, the participant's overall experiences and feelings using the ring during the trial, including any physical, mental or emotional concerns or experiences she encountered; her experiences using the ring and opinions about using it continuously for a month; her likes and dislikes; and her recommendations for future changes to the ring. The following details the process that should be used to collect, enter and process the SSI data.

For any technical problems accessing or using the MS Word template for the SSI or the FTP site, contact the MTN-013 RTI team at mtn013@rti.org.

B. Data Collection: Using the hard copy SSI form

1. Interviewers should use the **hard copy form** to record the participant's response **verbatim**, as provided by the participant. However, the essence and key points may be **summarized** by the interviewer for lengthy responses.
2. **Direct quotations** from the participant should be indicated with **quotation marks** to distinguish them from interviewer summaries.
3. The interview should **probe** to get more specific and detailed information in response to each question. This is a very important part of the interviewing process. For example, if a participant reports that use of the ring was "difficult," **probe to better understand** what she means by difficult (i.e. painful, interfering with daily life, physically hard, etc.).
4. Use as much **space** as needed to record participant's responses. Write responses on the reverse side of the form, in the margins, or on additional sheets of paper if necessary.
5. Once the interview is complete, the interviewer should quickly **review** the form for **completeness**, clarify with the participant any unclear parts or gaps in his/her notes; thank the participant, and escort her to the next stage of her visit.
6. Use the "**comments**" section at the end of the form to summarize how the SSI went, including the mood or affect of the participant during the interview.

C. Data entry: Using the SSI Word template

1. Interview notes should be transferred from the hard copy form to the SSI Word template on the same day as the interview. The Word template will make it possible for the data quality to be reviewed and later uploaded to Nvivo, a qualitative analysis software.
2. A PTID –specific SSI Word file should be created for each SSI conducted. To create a file for a participant, open the SSI Word template (**MTN013_SSI_PTID.doc**) and **save it as a NEW file**. When saving, keep the same file name but write over "PTID" with the actual numeric PTID. For example, for PTID 1001, the file name should be: **MTN013_SSI_1001.doc**.
3. The template is set up with **fields that appear GRAY** on screen. **PLEASE DO NOT MAKE ANY CHANGES TO ANY PART OF THE DOCUMENT**. Only enter data into the GRAY fields.

4. Enter the textual data (your hand written notes) in these fields by placing the cursor in the designated gray field in each section. For example, for the PTID, please enter only ONE number in each field until the complete PTID has been entered.
5. Enter the following in the designated fields at the top of the template: PTID, date of interview, interviewer initials, data entry date, and data entry staff initials. **The visit code should never be changed (10.0).**
6. Enter the participant's **responses** (based on your hand written notes) under each respective question by placing your cursor in the GRAY fields. All open-ended textual responses should be entered verbatim in **sentence case**, meaning not using capital letters. All direct quotations from participants should be written using quotation marks, as described above.
7. If a participant does not respond to a certain question, staff should type '**Did not answer**' in the response box.
8. Following data entry into the SSI Word file, the staff member should write '**Entered**' on the SSI paper form, write their initials and the date and file the SSI paper form in the participant.
9. **Note:** The SSI paper form is considered source documentation. Hand written notes on the source do not have to match the text in computer (i.e., if the answer to one question is written on the form under the heading of a different question, because of the conversational nature of the SSI, this is acceptable.)
10. The next step is to check for **spelling and grammatical errors** in the document. Please use the spell check feature in MS Word to check for spelling errors and review the document for any grammatical mistakes. Once the file has been fully reviewed, SAVE and upload to the FTP site as described in Section D below.
11. Add the file name and details to the Excel file log.

D. Data storage & transfer: Accessing files on the FTP (file transfer protocol) site

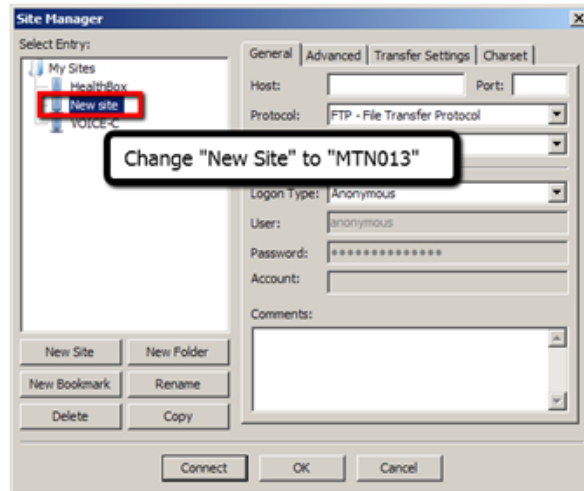
This section outlines three processes for using the FTP site:

1. Installing the FTP Client to access the FTP site
2. Uploading files to the FTP site
3. Downloading files from the FTP site

1. Installing the FTP Client to access the FTP site

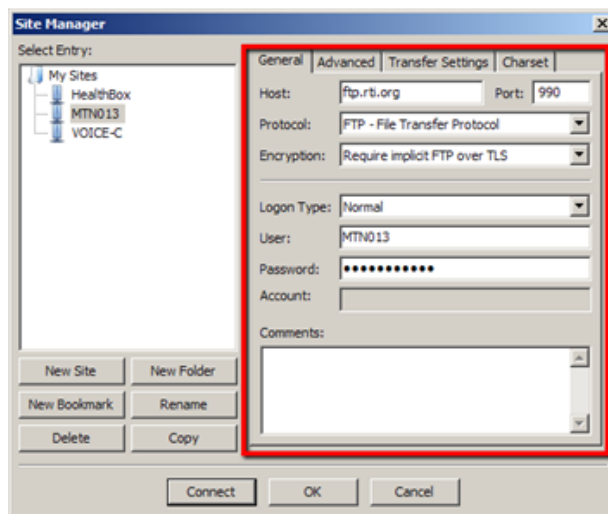
- a. Access and download 'FileZilla Client' from the following link: <http://filezilla-project.org/>
- b. Install the 'FileZilla Client' application by opening the *.exe file* which is downloaded from the site.
- c. Once installed, open the application, and click on '**File**' in the menu bar. Select '**Site Manager.**'
- d. A pop-up window will appear listing '**My Sites**' on the left and information fields on the right.
- e. Click on '**New Site**' (See **Image 1**). A new site will appear in that directory. In the directory, replace the name '**New site**' with the name: **MTN013**.

Image 1: Site Name



- f. Enter the below information for the MTN013 site in the data fields (See **Image 2**):
- Host: <https://ftp.rti.org>
 - Port: 990
 - Protocol: FTP-File Transfer Protocol
 - Encryption: Require Implicit FTP over TLS
 - Logon Type: Normal
 - Username: to be provided[†]
 - Password: to be provided

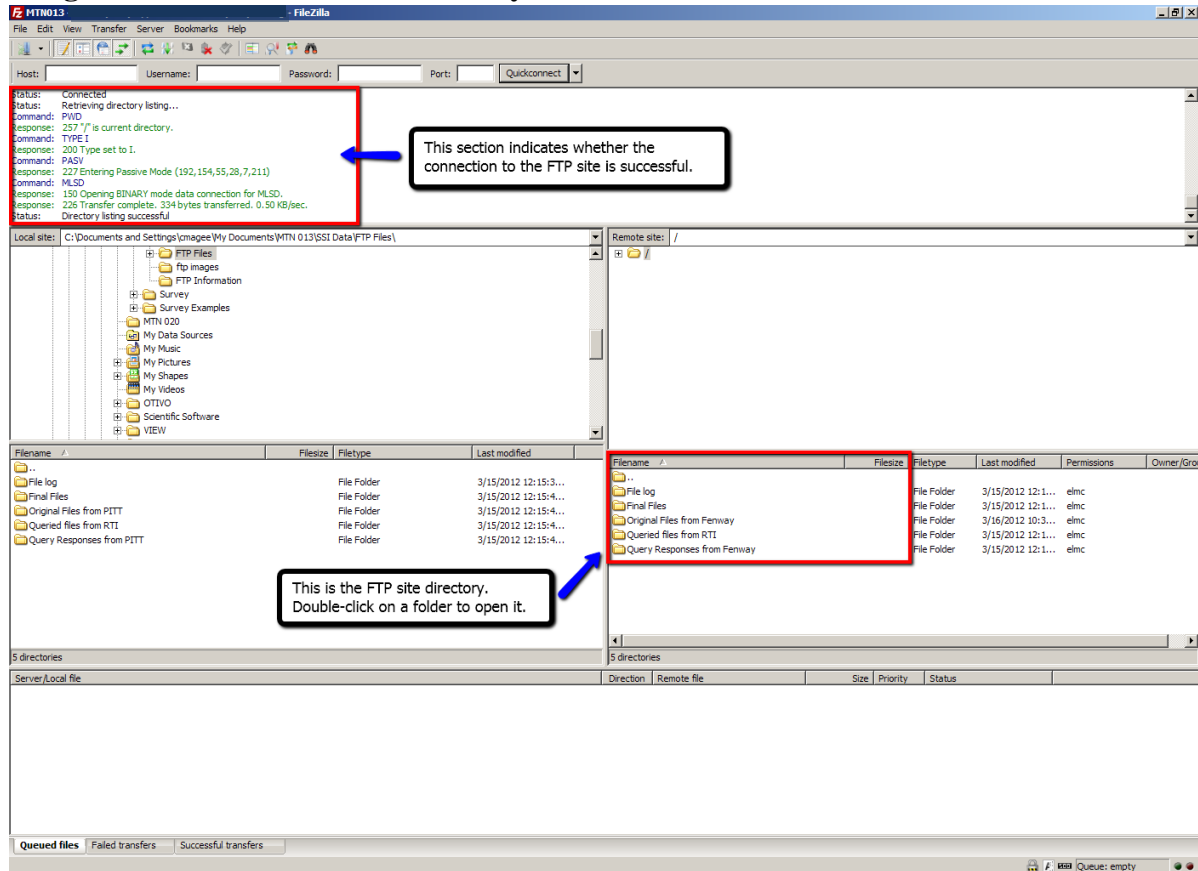
Image 2: Site Information



- g. Click '**Connect**' to initiate connection to the server. Once you are connected, the screen should appear as it does below in **Image 3**. The connection information will appear at the top of the screen, the user's computer directory will appear under '**Local Site**,' and the site directory will appear to the right within the '**Filename**' section.

[†] RTI will provide the username and password to each specific site for FTP access.

Image 3: Site Connection & Directory Window



NOTE: To reopen the site directory, go to 'File' menu and select 'Site Manager.' Double click on the FTP site name to open it.

2. Uploading Files to the FTP Site

- a. Once the MTN013 site directory is opened, a directory will appear listing all participating sites. Site staff should open their site folder to access its respective directory.
- b. The directories each have a series of four folders:
 - i. Original Files from Site
 - ii. Queried Files from RTI
 - iii. Query Responses from Site
 - iv. Final Files
- c. To add a file to the directory, simply drag the file to the correct folder on the FTP site. The file should automatically upload to the FTP site folder.

3. Downloading Files from the FTP Site

- a. Create a folder **on your computer** where you would like the SSI files to be downloaded.
- b. Next, go to the '**Local Site**' directory in the FTP window. This is the directory of all your computer's files. Expand the directory by clicking on the "+" sign next to each folder to find the folder **on your computer** where the file will be downloaded. (See **Image 4a.**)
- c. Then, double-click on the FTP site folder in the '**Filename**' section of the FTP window to find the file you want to download.
- d. Drag and drop the file **FROM** the FTP site (in the '**Filename**' section of the site window) **TO** the folder in the '**Local Site**' directory (your computer) where it should be downloaded. File should automatically download to that location. (See **Image 4b.**)

Image 4a: Preparing for file downloading

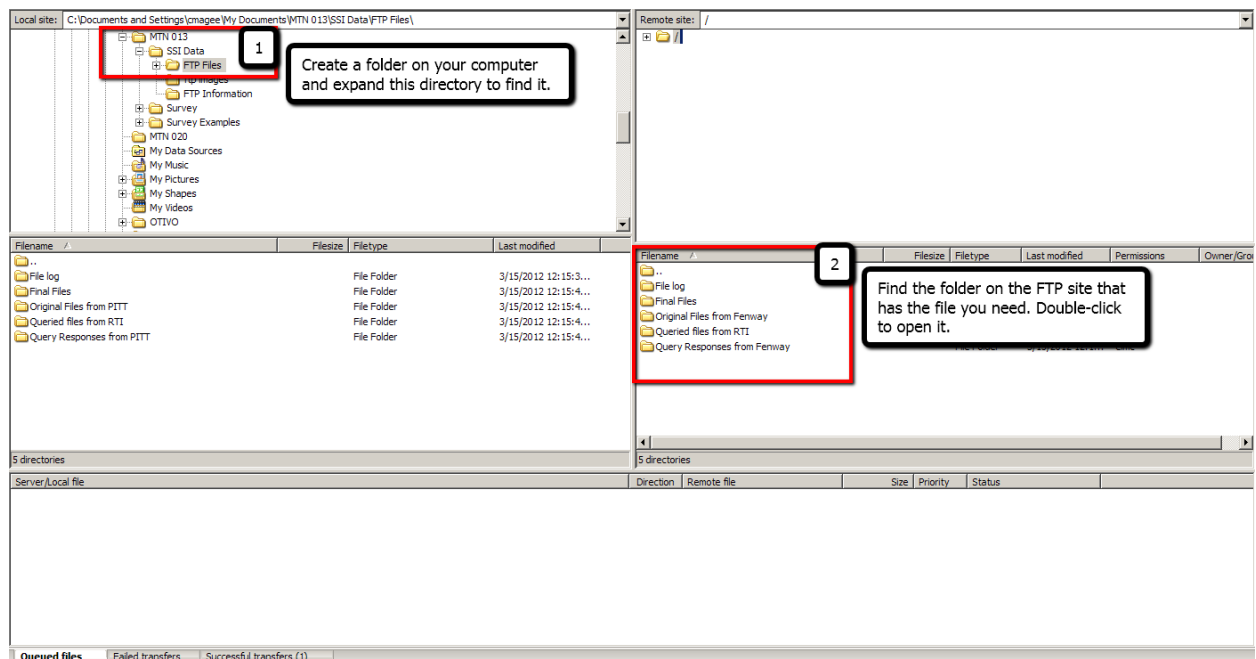
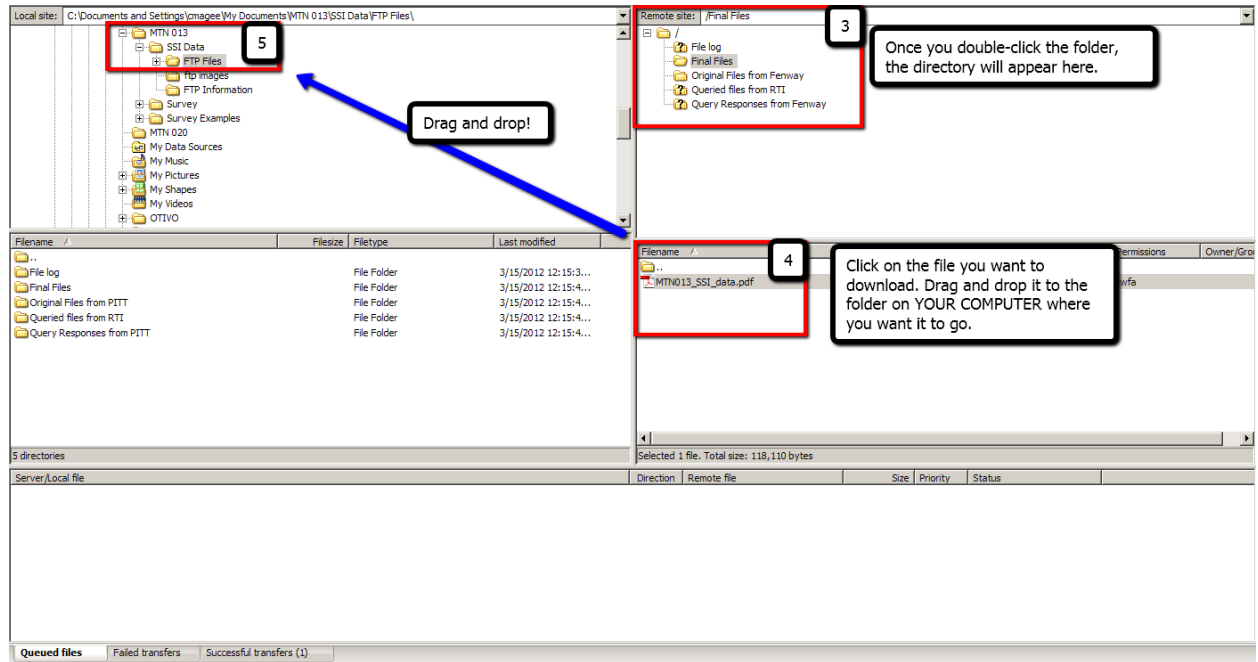


Image 4b: Drag and drop the file to download



E. Data Cleaning: Reviewing the data

1. Site staff and RTI will work together to review the data files and ensure that they are free of spelling and grammatical mistakes. The files will go through 4 stages:
 - a. Original data entry (original file)
 - b. Queried file (first review - by RTI)
 - c. Resolved queries (second review - by site)
 - d. Final files (all queries resolved)
2. **ORIGINAL FILES**
 - a. Once an SSI file is created for a PTID, that file is uploaded to the following folder on the FTP site: ***“Original Files from Site X.”***[‡]
 - b. Site staff sends the RTI team an email when new files are added to the FTP site for review.
3. **DATA LOG**
 - a. Site staff maintains a log of the completed SSI Word files in the Excel document template provided to the site by RTI. This file should be updated regularly and uploaded to the FTP server directory. **File logs** will be stored in the ***“File Log”*** directory.

[‡] “Site X” is a generic placeholder name for the specific site name. Each site will have its own directory listed under its name in which its files will be stored.

4. QUERIED FILES

- a. RTI reviews the files within the “Original File” directory for each site. These files are reviewed, or queried, for spelling and grammatical errors but are not edited for content.
- b. Queried files are renamed by RTI (see Table 1 for details) and uploaded to the FTP server in a folder designated for queried files, “*Queried Files from RTI.*”
- c. RTI sends site staff an email when new files are added to the FTP site for review.

5. QUERY RESPONSES

- a. Site staff downloads the queried files from the FTP server (see FTP site instructions) and reviews the requested changes and comments, communicating with the RTI team about any questions or concerns. Site staff makes corrections to the files as needed and updates the file name (see below for details).
- b. The files with responses from the site are then uploaded to the FTP server in the following folder: “*Query Responses from Site X.*”
- c. The site staff emails the RTI team to indicate that new files have been added to the FTP server.

6. FINAL FILES

- a. The RTI team reviews these corrected files. Once the file is considered final, the RTI team will create a final file and upload it to the FTP server to “*Final Files.*”
- b. RTI sends site staff an email when files are finalized.

Notes on filenames: Each time a document is edited, the editor should add their initials to the filename without changing any other part of the filename. The first time the file is named, there is no need to include the editor’s initials. It is only upon subsequent editing (cleaning) that this occurs. For example, when edited for the first time, “*MTN013_SSI_1001.doc*” would become “*MTN013_SSI_1001_CM.doc,*” and “*MTN013_SSI_1001_CM_NM.doc*” for the second revision. Once the document is finalized, all initials should be removed from the name and replaced with the word “FINAL,” as in “*MTN013_SSI_1001_FINAL.doc*” See **Table 1** below for details.

Table 1: File Naming - Examples for PTID 1001

File name	Data Stage
MTN013_SSI_1001.doc	Original data entry
MTN013_SSI_1001_CM.doc	RTI query for spelling & grammatical errors (first review with first reviewer’s initials included)
MTN013_SSI_1001_CM_AS.doc	Site query response (second review with second reviewer’s initials)
MTN013_SSI_1001_FINAL.doc	Final cleaned document (all initials removed)