

Section 6 - Counseling and Behavioral Considerations

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This section contains guidance on the following types of counseling provided in MTN-017:

- HIV Pre- /Post-Test Counseling
- Risk Reduction Counseling
- Study Product Adherence and Product Use Instructions Counseling,
- Protocol Adherence Counseling,
- Rectal Biopsy/Fluid Procedural Counseling (rectal biopsy/fluid subset only)

Each of these types of counseling is required at most if not all study visits. All counseling should be provided in a non-judgmental participant-centered manner that responds to current participant needs for information, education, support, skills building, and/or referrals. Participants' needs are likely to change over time; counseling provided should also change over time accordingly.

All counseling should be documented in participant study records. Proper documentation may be achieved through the use of counseling checklists, worksheets, and other tools, as well as counselors chart notes. To support ongoing participant-centered counseling over time, documentation of each counseling session should include sufficient information and detail to inform and guide the participant's next counseling session.

During counseling, a worksheet or site-specific tool may be used to guide any of the counseling sessions. During the session, counselors should engage in the discussion rather than focusing on taking notes. A summary of the counseling session should be written once the session is completed.

6.1 HIV Pre- /Post-Test Counseling

HIV testing is required at each scheduled MTN-017 study visit except the Initiate Period 2 and Period 3 visits. HIV pre-test and post-test counseling is required at each visit in which HIV testing is performed. The sample [HIV Counseling Worksheet](#) available on the MTN website provides a guide to the minimum requirements for MTN-017 HIV and risk reduction counseling sessions; this worksheet may be tailored for use at all study sites.

All HIV counseling should be provided in accordance with local counseling standards. Study staff who provide HIV counseling should be trained to do so per local practice standards. Counseling staff should also be trained on study-specific HIV testing methods and interpretation of test results per the testing algorithms in protocol Appendix II. Information on interpretation of screening, enrollment, and follow-up test results is provided in Table 6-1a and Table 6-1b. These tables should be referenced as needed when providing pre-test and post-test counseling. Given that HIV counseling will be provided at nearly all MTN-017 study visits, when providing pre-test and post-test counseling, it is especially important to avoid repetition of the same information at each counseling session. Participant-centered approaches should be used to assess participant knowledge of relevant information, dispel any misconceptions, ensure participant readiness for HIV testing, and ensure participant understanding of test results.

Table 6-1a
Interpretation of HIV Rapid Test Results
Per Protocol Appendix II

Test Result	Interpretation
Both rapid tests negative	HIV-uninfected; test results indicate that you are not infected with HIV.
Both rapid tests positive	HIV-infected; test results indicate that you are infected with HIV. During follow-up additional protocol-specified testing is required to confirm results.
Discordant rapid tests (one negative, one positive)	HIV status not clear; test results indicate that you may be infected with HIV but additional testing is needed to confirm your status. (Please note, for screening participants, a participant is not eligible if results are discordant.)
Western blot negative	HIV-uninfected; test results indicate that you are not infected with HIV.
Western blot positive	HIV-infected; test results indicate that you are infected with HIV.
Western blot indeterminate	HIV status not clear; test results indicate that you may be infected with HIV but additional testing is needed to confirm your status.

Table 6-1b
Interpretation of HIV EIA Test Results
Per Protocol Appendix II

Test Result	Interpretation
EIA tests negative	HIV-uninfected; test results indicate that you are not infected with HIV.
EIA tests positive	HIV-infected; test results indicate that you are infected with HIV. During follow-up additional protocol-specified testing is required to confirm results.
EIA Indeterminate	HIV status is not clear; additional testing is needed to confirm your status. (Please note, for screening participants, a participant is not eligible if results are indeterminate.)
Western blot negative	HIV-uninfected; test results indicate that you are not infected with HIV.
Western blot positive	HIV-infected; test results indicate that you are infected with HIV.
Western blot indeterminate	HIV status not clear; test results indicate that you may be infected with HIV but additional testing is needed to confirm your status.

6.2 Risk Reduction Counseling

Risk reduction counseling is required per protocol at all visits with the exception of the Initiate Period 2 and 3 visits. Participant-centered approaches should be used when assessing participant risk for HIV and STI infection and providing risk reduction counseling. The counselor should ask open-ended questions, actively listen to participant responses, probe as needed for further information, and guide the participant in identifying his/her risk factors and barriers to risk reduction, as well as strategies and action plans to try to address these.

Supported and facilitated by the counselor, the risk reduction plans identified by the participant should reflect and respond to his/her current risk assessment and should be practical, yet challenge the participant toward further risk reduction. For participants whose risk reduction barriers are significant, risk reduction plans may need to be incremental. For participants whose risk reduction barriers change over time (e.g., due to a partner change), risk reduction plans may need to change over time. Importantly, all risk reduction plans should be agreed upon by the participant and should be documented in the participant's study records, with a copy made available to the participant if he/she wishes. The sample [HIV Counseling Worksheet](http://www.mtnstopshiv.org/node/4524) posted on the MTN website (<http://www.mtnstopshiv.org/node/4524>) incorporates a structure that counselors may find helpful for documenting current risk factors and barriers, experiences with risk reduction since the last session, and risk reduction plans until the next session. At each counseling session, the risk factors and risk reduction plans identified at the previous sessions should be reviewed and discussed with the participant to determine:

- What was the participant's experience since the last session?
- Was the participant able to carry out strategies and plans?
- What were the outcomes?

Risk reduction plans identified and agreed upon with the participant at the current session should then build on experience since the last session:

- Successful strategies should be continued
- Additional strategies may be identified to achieve further risk reduction
- Alternative strategies may be identified if strategies tried since the last session were not successful

Risk reduction counseling sessions should also offer skills building to the participant when indicated, e.g., on how to use condoms, how to discuss sensitive issues with partners and other influential persons. HIV/STI risk reduction counseling for partners should always be offered, either as an individual session or as a couple's session.

Referrals are expected components of risk reduction plans when indicated based on participant needs. When referrals are provided, these should be fully documented in participant study records and should be actively followed up at subsequent counseling sessions to determine whether the participant sought the services to which s/he was referred, what the outcome of the referral was, and whether additional referrals are needed. All such follow-up should also be fully documented in participant study records.

6.3 Product Use Instructions and Protocol Adherence Counseling

Participants will be provided product use instructions and protocol adherence counseling for the first time at their study enrollment visit (Initiate Period 1 Visit). The person providing product use instructions and protocol adherence counseling will inform participants of study requirements for product use and adherence to protocol requirements such as returning for study visits and not sharing product. The staff person providing product use instructions and protocol adherence counseling should NOT be the same person who provides participant-centered product adherence counseling (refer to section 6.5 below for more information). This is to ensure honest and accurate reporting of potentially less than perfect product use by participants to the product adherence counselor.

After being informed of their study regimen sequence, participants will receive their first dispensing of study product and detailed regimen-specific product use instructions which have been translated into local languages at each site and illustrated to optimize participants' understanding. In addition to verbal instructions, a copy of the illustrated instructions should be provided to each participant at each of the Initiate Period visits. Other visual aids, such as sample tablet bottles, sample applicators, sample applicator cartons, product photographs, study-specific fact sheets, and the informed consent support booklet should be used as needed when providing instructions to help ensure participant understanding of proper product use.

Adequate time should be taken to explain the product use instructions thoroughly and to answer any questions the participant may have. Any questions or concerns raised by the participant should be documented in his/her study records so this information is easily available for reference at follow-up visits.

6.3.1 First Dose at the Initiate Period Visit for Each Product Use Regimen

All study participants will complete their first product use or simulation of their first product use of their assigned study regimen at the study clinic during their Initiate Period Visits. Simulation of product use refers to inserting an empty applicator (an applicator without any study product) to allow the participant to practice applicator insertion. The rationale for this is to help ensure participant understanding, comfort, and confidence with proper product use from the very beginning of study participation. In particular, any questions or concerns that arise in the context of first product use can be addressed by study staff before the participant is required to use study product on his/her own.

After providing product use instructions and answering any questions the participant may have, study staff will ask the participant if s/he is ready to try taking the tablet or inserting the gel applicator. If the participant has any further questions or concerns, these should be documented for future reference and addressed by study staff. When the participant is ready, s/he should then be instructed to continue with first product use as follows:

- **For participants initiating the daily rectal gel regimen who are NOT in the rectal fluid/biopsy subset**, the first insertion can either be performed in the study clinic or a simulated insertion can occur, depending on participant's preference and level of comfort. Participants can choose to do the first insertion either in a private space, (no direct observation of gel insertion) with study staff standing by in case the participant requests guidance or technical assistance, or in a private space with direct staff observation. Study staff should remind the participant to discard the used wrapper and applicator in the bin provided.
- **For participants initiating the RAI-associated rectal gel regimen who are NOT in the rectal fluid/biopsy subset**, the first insertion should be simulated only and participant should be provided clear instructions that first product use should occur around the time of sex.

Note: Inability to insert the gel applicator is expected to be very rare. For participants who have difficulty, study staff should provide further information and guidance to address any difficulties encountered, and should provide one or more empty applicators for additional hands-on practice by the participant. After guidance is provided, and further practice takes place, the participant should try again to insert the gel applicator. Throughout this process, study staff should avoid handling dispensed gel applicator supplies.

- **For participants initiating the daily oral regimen**, the first dose should be directly observed by study staff. A private space is not required. Study staff should remind the participant to leave the desiccant inside the bottle(s) but discard the bottle seals and cotton wool in the bin provided.

Note: Inability to swallow tablets is expected to be rare. For participants who have difficulty, study staff should advise the participant to:

- Take a sip of water or juice and relax
- Place the tablet at the back of the tongue and swallow it with water or juice
- Try drinking water or juice with a straw

After guidance is provided, the participant should try again to take the study tablet. Throughout this process, study staff should avoid handling dispensed tablet supplies.

Study staff should NOT perform any steps in the product use instructions for the participant. Study staff may answer questions, and/or provide prompts or reminders to the participant, but otherwise should limit their involvement to ensure that the participant is able to perform each step on his/her own before leaving the clinic.

For all participants, if more than one gel applicator, or more than one tablet is used at the enrollment visit, study staff must document this in chart notes and must also inform pharmacy staff, so this information can be taken into account when accounting for the participant's study product supplies at his/her next study visit. In this situation, staff must also ensure the participant still has the minimum quantity of product necessary until his/her next scheduled visit.

After the participant completes the first product use, but before proceeding to adherence counseling, study staff should de-brief with the participant on the first product use experience. If the participant has any questions or issues, these should be documented so the information is easily available for reference at study follow-up visits.

6.3.2 First Dose at the Initiate Period Visit for Participants in the Rectal Biopsy/Fluid Subset

Participants in the Rectal Biopsy/Fluid Subset will have biopsies collected at Enrollment. Since these participants will be instructed to abstain from inserting anything into the rectum, including abstaining from using the study gel and having receptive anal intercourse (RAI) for 72 hours (3 days) after collecting of biopsies, participants whose first regimen is rectal gel (daily or RAI-associated use) will be instructed to start product use 72 hours (3 days) after the Enrollment visit. During the Enrollment visit, these participants will be provided instructions on how to insert the gel, do a simulation of first dosing at the clinic, and discuss any questions or issues they may have.

Participants whose first period is the daily oral regimen will be asked to take the first dose at the clinic during the Enrollment visit as above.

The initial dosing of the second and third study product regimens, at Initiate Period 2 and 3 Visits, do not have the same restrictions since biopsies are not collected at those visits. Therefore, participants will be instructed to insert the gel or simulate insertion of the gel in the study clinic (as described above) at the Initiate Period 2 and 3 Visits.

6.3.3 Protocol Adherence Counseling

Protocol adherence counseling is required at each Initiate Period and Mid-Period visit. As safety is of the utmost importance, site staff will counsel participants to refrain from engaging in certain practices during the course of study participation.

Per protocol, participants should be counseled to refrain from the following:

- Engaging in sexual activity (receptive or insertive intercourse) with another study participant
- Engaging in penetrative intercourse without the use of study-provided condoms
- Participating in other studies involving drugs, medical devices, vaccines or genital products for the duration of study participation
- Sharing study product with others

6.4 Counseling on Collection of Rectal Biopsies for Participants in the Rectal Biopsy/Fluid Subset

At selected sites, participants in the Rectal Biopsy/Fluid subset will undergo collection of biopsies for PK, PD, and Immunological sample collection starting at the Enrollment visit (Initiate Period 1 visit). At these visits, study staff will explain what procedures will be performed at the visit and what to expect.

Participants will be counseled that a rectal biopsy is a procedure to remove a small piece of rectal tissue (about the size of a grain of rice) for examination. At Enrollment, approximately 15 biopsies will be collected and during follow-up approximately 20 biopsies will be collected. In addition, participants will be informed that in preparation for this procedure they will receive an enema in order to empty their bowels completely. This will allow the clinician a clear view of the rectum. Then a lubricated flexible sigmoidoscope is placed into the rectum. Site staff should explain to participants what a flexible sigmoidoscope is and its purpose. A picture of the flexible sigmoidoscope is recommended during counseling for reference. Participants should be counseled that they may experience some cramping or mild discomfort during the procedure, and they may feel an urge to have a bowel movement as this sensation occurs as the instrument is placed into the rectum.

Participants in the Rectal Biopsy/Fluid subset should be counseled to abstain from inserting anything into the rectum, including using the study gel and having receptive anal intercourse for 72 hours (3 days) after the collection of these samples. Participants should also be counseled to refrain from the use of NSAIDs, aspirin and/or other drugs that are associated with the increased likelihood of bleeding for 72 hours (3 days) prior to and following sample collection.

6.5 Real –Time Adherence Monitoring and Counseling

Participants will be counseled during the informed consent process and at each subsequent scheduled follow up visit of the importance of taking the study product(s) as instructed by study staff. Participants will be informed that during their participation in the study, blood, rectal fluid and, if applicable, rectal tissue will be collected to test for how much of the study product is in the body. Participants should also be informed that this blood testing will be routinely done during the participant's study participation, and the results of this testing (PK result) will be discussed with the participant at study visits when they become available. Test results for the amount of product in the rectal fluid and/or tissue, if applicable, will not be available until after a participant has completed his/her study participation. Participants should be encouraged to ask any questions or share concerns they have about taking the study product as directed.

6.6 Participant-Centered Product Adherence Counseling

Adherence counseling will be conducted based on participant-centered strategies in order to reinforce the value of accurate reporting of adherence to study product use. The counselors at each site will be trained by personnel from Columbia University. Training will include role-playing and monitoring of the first several sessions. The adherence counseling sessions will consist of several components that vary by visit type, as outlined in this section.

Please see section 2 of this manual for further guidance related to reporting requirements for protocol deviations associated with study product non-use. Please note that partial use of study product does not meet criteria for a protocol deviation. For cases in which participants report partial use of study product, in the context of participant-centered product use adherence counseling, staff should discuss and document the participants' experiences with product use including what makes it easier or harder for him/her to use the study product as recommended. Participant-centered product use adherence counseling including all steps taken/strategies developed taken by the participant to address improve product use should be documented in source documents and/or chart note.

6.6.1 Visit-Specific Counseling Sessions

6.6.1.1 Initiate-Period Visits

At the Initiate-Period Visits, counselors will provide an overview of product adherence counseling to the participant, emphasizing their appreciation for the participant in helping researchers better understand how the study products might be used by the community and explaining the importance of accurate reporting, even if the participant is not fully adherent. The counselor will gauge the participant's understanding of product use instructions, assess the participant's

confidence with using the study product as indicated, and work with the participant to identify potential obstacles to using the product as indicated and how they might be overcome.

6.6.1.2 Mid-Period Visits

At the Mid-Period Visits, the counselor will begin by conducting the Data Convergence Interview, consisting of reviewing and converging adherence data, based on product counts and SMS data, with participant input. In addition, when blood PK results are available, the counselor will work with the participant to converge the PK result with the product count and SMS data. These data convergence procedures are explained in more detail below in Section 6.7.4. After working with the participant to converge these three adherence measures (product count, SMS, and PK result), the counselor will explore with the participant his/her experiences using the study product, his/her willingness to improve adherence to the product, and ways to improve adherence, if s/he wishes. The counselor will emphasize that the study team will learn a lot not only from participants who can use the products as recommended but also from participants who encounter difficulties. The latter will contribute information on how the product or the regimen can be improved. Therefore, accurate reporting is more important than perfect adherence.

6.6.1.3 End-Period Visits

At the End-Period Visit, the counselor will again begin by conducting the Data Convergence Interview to review and converge adherence data, based on product counts and SMS data, and will converge prior use reports with blood PK results, when available. Finally, the adherence counselor will explore what, if anything, helped the participant to adhere to product use and whether these approaches might be helpful to the participant in the next period of the study.

For a product adherence counseling script and related tools, please see the [Participant Centered Product Adherence Counseling Manual](#) available on the MTN website.

6.7 Behavioral Measures

There will be four types of behavioral measures in MTN-017:

- 1) the Web-based Computer Assisted Self-Interview (CASI) Questionnaires;
- 2) the Short Message Service (SMS) Diary;
- 3) the In-depth Phone Interviews, completed with a sub-sample of participants; and
- 4) the Data Convergence Interviews (product counts and SMS data), and PK Data Convergence Interview (product counts, SMS and blood PK data).

Information on the timing of the CASI questionnaires, SMS Diary and In-depth Phone Interviews are presented in Table 6-2 in section 6.7.3. Information on the timing of the Data Convergence Interviews is presented in Table 6-3 in section 6.7.4.

Note: Participants who permanently discontinue study product are required to complete the Follow-up CASI questionnaire that corresponds to the study product regimen (daily gel, RAI-associated gel use, or daily oral) for which the participant received his/her last dispensation of study product at the visit in which study product is first held/discontinued, or at the visit in which site staff first learn that the participant has stopped or intends to stop study product use. Study staff should complete required behavioral assessments for the visit in which product is discontinued, including CASI questionnaires, Data Convergence Interview and/or PK Data Convergence Interview. These procedures will be discontinued for the remaining study visits that occur during the hold, or after permanent discontinuation. See Section 5.6.4.1 for further information.

6.7.1 Web-based CASI

6.7.1.1 Web-based CASI Description

Data entered from the site's study computer are transmitted instantly to SCHARP's server. The questionnaires are not accessible to people who are not participating in the study. The MTN-017 Web-based CASI includes the Baseline Behavioral Questionnaire and the Follow-up Behavioral Questionnaires. The Baseline Behavioral Questionnaire will collect information on each participant's sexual behaviors, use of rectal products, drug and alcohol use, smoking history, risk perception, and anticipated likelihood of microbicide use before trying the product. The Follow-up Behavioral Questionnaires are tailored to each study product regimen (daily oral, daily gel, or RAI-associated gel use) and will collect information on each participant's acceptability of the study product, including liking the product, ease of use, likelihood to use after having tried the product, experiences using the study product during the trial, sexual behavior, adherence, use of rectal products, recommendations, and feedback on the SMS Diary. All participants will be asked to respond to Web-based CASI questionnaires.

6.7.1.2 Web-based CASI Preparation

Based on the visit number and study period, determine which questionnaire the participant will need to take. The Baseline Behavioral Questionnaire will be administered upon enrollment. The Follow-up Behavioral Questionnaires will be administered at the End Period Visit for each study period. Make sure to have on hand the participant's study ID and the appropriate web link (See below for Web-based CASI Procedures) to access the questionnaire online.

6.7.1.3 Web-based CASI Equipment

Each study site will have a computer connected to the Web for the participants to use. Sites should select a location in the research offices for the computer that is private (i.e., the screen should be out of sight to staff members or other participants while answers are being entered), but allows study staff to be nearby to answer questions or assess whether the participant is having computer problems. As such, staff members should be familiar with the questionnaire in case participants raise any questions. There should be an electrical outlet and a jack for broadband connection, unless a reliable wireless connection is used. The computer should be plugged into an AC power source. An external mouse may be connected to the laptop. To minimize problems with computers, keep them plugged into a power source, avoid having food or drink nearby, and keep the area where the computer is used clutter-free.

You should have an anti-virus program installed on your computer. Also, please make sure to turn off the AutoComplete option for the Internet browser you will use to administer the CASI questionnaires. This is very important, as it will prevent participants from viewing answers previously entered into the questionnaires. If you are using Internet Explorer, go to Tools, then Internet Options, then Content, then AutoComplete Settings, and uncheck all boxes.

It is recommended that each site have a back-up computer available for use in the event that the designated computer does not work. Each site is responsible for addressing issues of security, privacy, background noise, lighting, ergonomics, and overall participant comfort in its site-specific study operating procedures.

6.7.1.4 Web-based CASI Procedures

To begin, access the Web page for the appropriate questionnaire using Internet Explorer, Firefox or another compatible browser and enter the following URL:

Baseline Behavioral Questionnaire:

- <http://www.scharp.org/MTN017/baseline>
- http://www.scharp.org/MTN017/baseline_spanish
- http://www.scharp.org/MTN017/baseline_thai

- http://www.scharp.org/MTN017/baseline_xhosa
- http://www.scharp.org/MTN017/baseline_afrikaans

OR

Follow-up Behavioral Questionnaires:

- www.scharp.org/MTN017/followuptablet
- www.scharp.org/MTN017/followupdailygel
- www.scharp.org/MTN017/followupRAIgel

Please note: above links for Follow-up Behavioral Questionnaires are in English. For other languages, add [_] and language name as shown above for the Baseline Behavioral Questionnaire.

Each PTID may only be used one time for each CASI questionnaire. The Baseline Behavioral Questionnaire should be done, ideally, on the day of randomization. If a participant needs to rescreen and take the Baseline Behavioral Questionnaire for a second time, access the Repeat Baseline Behavioral Questionnaire via the following links:

- www.scharp.org/MTN017/repeatbaseline
- www.scharp.org/MTN017/repeatbaseline_afrikaans
- www.scharp.org/MTN017/repeatbaseline_spanish
- www.scharp.org/MTN017/repeatbaseline_thai
- www.scharp.org/MTN017/repeatbaseline_xhosa

Please make sure to document in the Comments section at the end of the questionnaire the reason for repeating the Baseline Behavioral Questionnaire.

Once the questionnaire is accessed, staff should complete the following:

- 1) Log in by entering the PTID, Study Code (MTN017) and re-entering the PTID for confirmation.
- 2) If the participant is completing a Follow-up Behavioral Questionnaire, you will be asked to confirm the regimen with the participant (daily oral, daily gel, or RAI-associated gel use) before entering the visit code.
- 3) Enter the visit code assigned to the visit. Refer to the Data Collection Section of the SSP for a complete list of visit codes.
- 4) If the participant is at Visit 10 or an Early Termination Visit, select the option for the Final Visit. An additional set of questions asking participants to compare all study conditions and to provide feedback on the SMS Diary will be presented at the end of the questionnaire.
- 5) For quality control, confirm with the participant that the information entered regarding the number of periods completed is correct.
- 6) Enter the current date by selecting the day, month and year from the drop down menus.
- 7) Since the year 2015 is not available from the pull-down menu, please select the year 2014 and the correct month and day for dates in 2015. Since each survey is time-stamped, we will be able to distinguish the date during data analysis. (For more information, see Data Communiqué #7, available at: <http://www.mtnstopshiv.org/node/4643>)
- 8) Instruct the participant to follow the online instructions for using both the keyboard and mouse, as well as moving from page to page to answer questions (i.e., using the "Next" button).
- 9) Verify the participant's comfort with using the mouse and keyboard, and navigating through the questionnaire.

- 10) Initially, the participant will be presented with simple practice questions (e.g. “choose all that apply”, “indicate how many times”, “choose one of a fixed set of answers”, etc.) Allow the participant to complete the practice questions, assisting him/her if needed, to make sure he/she understands how to answer 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 (i.e., numbers that are out of the possible range, e.g., a participant reports having used the gel 100 times).
- 11) Let the participant know that he/she can refuse to answer any question. However, if the participant is unsure of his/her answer, encourage the participant to make the best guess rather than refuse. Answer any questions that the participant may have and let him/her know that you are available for help.
- 12) Instruct the participant to let you know once a message appears at the end of the questionnaire indicating that he/she has completed the questionnaire (the note states: **Please notify the study staff that you are finished**), or if he/she needs or wants to stop the questionnaire before reaching the end.
- 13) Leave the room and allow the participant to complete the Behavioral Questionnaire responding on his/her own. The participant should be the only person in the room at the time he/she is completing the questionnaire.
- 14) When the participant calls you, enter the password: 2011 for the Baseline Behavioral Questionnaire and 2012 for the Follow-up Behavioral Questionnaires.
- 15) Use the comments field on the following screen to enter information about any deviations from the behavioral measures section of protocol (Section 7.10) or any problems with the web-based questionnaire. You may leave this field blank if there are no problems of note.
- 16) Close the browser window when you have completed all of the above steps.

6.7.1.5 Web-based CASI Troubleshooting

If you encounter any problems with the Web-based CASI questionnaires, either accessing them or completing them, or with the laptop/desktop that you are using, notify the team by sending an email to the alias list mtn017webtrouble@mtnstopshiv.org. The team of staff members (Karen Patterson at SCHARP and Curtis Dolezal and Rebecca Giguere at Columbia University) will be available to assist you to troubleshoot and resolve any problems you may have with the Web-based questionnaires.

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. It is very useful to the MTN-017 Web Trouble team to have an exact copy of error messages. To take a snapshot of an error message presented on the screen, simply maximize the screen containing the error message by clicking on the middle box containing one square located at the top right corner of the screen, and then hit Control (CTRL) and Print Screen (or PRT SC on most laptops) simultaneously on your keyboard to create an image of your screen. Next, open Microsoft Word and paste your image into the Word document (click on Edit and then Paste; or simply hit CTRL and V simultaneously). Save the Word file as MTN17WebProblem[insert date].doc and attach it to your email to the MTN-017 Web Trouble team. An example of an email message to the Web Trouble team is presented below.

Email Message:

To: mtn017webtrouble@mtnstopshiv.org

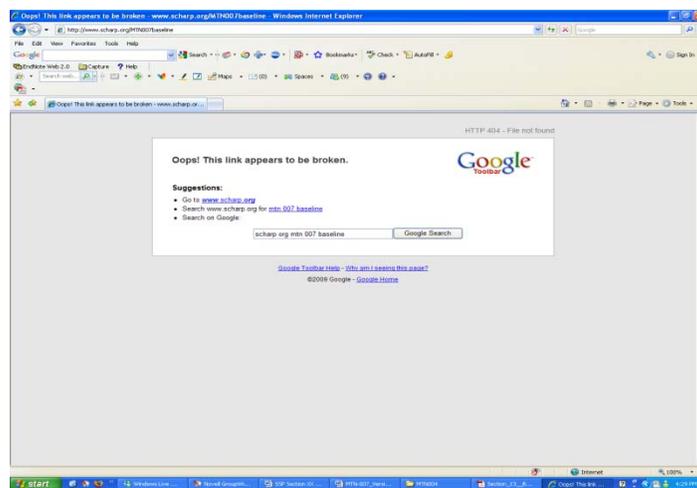
From: XXX

Date: July 30, 2012, 10:28am EST

Re: MTN 017 Web Problem

No access to the Baseline Behavioral Questionnaire (www.scharp.org/MTN017baseline) on July 30, 2012 at 10:20am EST. A participant is expected in for a study visit at 11:00 am and will be ready to complete the questionnaire at 11:30am. HELP!

[Word document containing an image of the error message generated using Ctrl + Print Screen should be attached to the email (example of filename: MTN017WebProblem_7-30-12.doc)]



Rebecca Giguere will coordinate efforts to quickly resolve any problems. She will keep a record of any problems in a log (MTN-017 Web Troubleshoot Log), track actions taken to correct problems, and inform and follow up with team members, as appropriate. For any technical problems accessing the questionnaires, site study staff should contact the SCHARP Atlas group by e-mailing atlas@scharp.org.

If a participant is answering the questionnaire and encounters a problem, exit the questionnaire by closing the browser page and then access the appropriate link to the Web page again to log in the participant. The system should return to where the participant left off (i.e., the Web page with the question where a participant left off should be displayed). If the problem persists, contact mtn017webtrouble@mtnstopshiv.org and call Rebecca Giguere so that actions can be taken immediately. The MTN-017 Web Trouble team will assess the problem and communicate with you about resolutions. If the problem cannot be resolved quickly, a participant appointment should be made as soon as possible, preferably within a day or two, so that the participant can return to the site to complete the questionnaire. If this occurs, document the incident in the participant's file and inform Rebecca Giguere to add it to the MTN-017 Web Trouble Log.

6.7.2 SMS Diary

6.7.2.1 SMS Diary Description

The SMS Diary will be administered to all participants and will be used to collect information about participants' use of study product starting at the enrollment visit (Visit 2). Participants will indicate at what time of the day they want to receive the reminder (they will be encouraged to match the time of the reminder to the time of the day they expect to self-administer a product dose). A central server will be programmed to generate text messages around that time with a few short questions answerable with a couple of keystrokes. Participants will be asked to respond

to the SMS daily and answer one question on their use of study product. The information collected will be used to measure each participant's adherence to product use. SMS Passwords, corresponding to PTIDs, will be used for the SMS system. Also, 10 mock SMS Passwords are provided per site for testing and troubleshooting purposes, and are available in Appendix 2. Each site will be provided their respective SMS Password List via email.

When a participant has not sent any message to the system in 48 hours, a staff member of the behavioral team at Columbia University will alert the study staff at the site. The study staff should then contact the participant to inquire about missed text messages (if the participant forgot to send any) and his/her adherence to the study product regimen, and to remind the participant to respond to the SMS Diary reminders immediately after receiving them.

6.7.2.2 SMS Diary Preparation

At the screening visit (Visit 1), site staff should complete the [SMS Readiness Assessment](http://www.mtnstopshiv.org/node/4524) (available at: <http://www.mtnstopshiv.org/node/4524>) with each eligible participant to determine whether the participant has a cell phone he/she can use to respond to the SMS Diary or if the site will need to provide one. The [SMS Readiness Assessment](http://www.mtnstopshiv.org/node/4524) will also allow staff to determine each participant's familiarity with sending and receiving text messages so that the appropriate level of training can be provided at Visit 2. Prior to the enrollment visit (Visit 2), study staff should have ready the site-specific access number for the SMS Diary, the participant's password, a cell phone for the participant if needed (see SMS Diary Equipment), and the [Texting 101 Guide](http://www.mtnstopshiv.org/node/4524) (available at: <http://www.mtnstopshiv.org/node/4524>) or User's Guide for the cell phone being provided, if the participant is unfamiliar with text messaging.

Once a site begins conducting follow-up visits, a designated member of site staff should download and print on a daily basis (the morning of each work day) the site's SMS Data Sheet from the site-specific page on SCHARP's Atlas website (available at:

<https://atlas.scharp.org/cpas/project/MTN/017/Audio%20and%20SMS%20files/begin.view?>).

After entering the Atlas website via the link and logging in, select your site name from the list on the left. Then scroll to the bottom of the page and select the folder labeled "SMS Files." You can then click on the Excel spreadsheet containing the cumulative SMS Data for each participant at your site.

This information will be used for completing the first page of the Data Convergence Interview (non-DataFax) CRF and conducting the actual interview. It is recommended that sites download the SMS Data Sheet on a daily basis so that this data is available as needed, and so as not to delay the interviews in order to obtain this information. The sheet will be updated and uploaded to the site's MTN-017 SCHARP Atlas page on a daily basis (Monday through Friday, US-Eastern Time) by members of the Behavioral Research Working Group (BRWG). It will contain a summary of all SMS data received to date for each study participant at the site, and will show, for each PTID, the number of reports completed, number of times product was used, whether the participant qualifies for the bonus, and the start and end dates. At a given visit, site staff should calculate the amount of compensation due to a participant based on the number of reports completed and whether the participant qualified for the bonus. Participant information (SMS and compensation) can also be requested by e-mail from mtn017sms@mtnstopshiv.org when necessary.

6.7.2.3 SMS Diary Equipment

Participants who do not have a cell phone available for study use may be given an inexpensive mobile phone for use during the study. Participants may be told that there is no replacement for lost phones in the first 8 weeks of the study. (If they lose the phone after 8 weeks, decisions on phone replacement will be made on a case-by-case basis based on compliance with reporting during the prior 8 weeks). Participants will be required to return the study-provided cell phones at Visit 10.

6.7.2.4 SMS Diary Procedures

At the Initiate Period Visits (Visits 2, 5 and 8), study staff will provide the participant with general use instructions and train the participant on using the SMS to report gel or tablet use during the 8 weeks he/she is using the product. The training should be done using the cell phone that the participant will use during the study (please make sure to remind participants who will be using their own cell phones to bring them to their study visit). Site staff should follow the general use instructions below as well as the training script available on the MTN-017 webpage under Study Implementation Materials.

General Use Instructions:

- 1) Inform the participant that the study procedures include responding to a brief text message about product use on a daily basis, and that s/he will receive compensation per SMS session (compensation varies by site). If the participant misses reporting on less than four days per month during each product use period, s/he will also receive a bonus. Otherwise, s/he will receive the full amount accumulated per SMS, but not the bonus.
- 2) Based on the SMS Readiness Assessment, determine whether the participant will receive the messages on his/her phone or a phone provided by the study. If s/he chooses to use his/her phone, s/he may be compensated more per reporting session to offset any costs.
- 3) Inform the participant that he/she can choose the most convenient time of the day to get the text message and this time will be programmed once s/he joins the system (he/she should choose a time on the hour). Tell him/her that, ideally, the message should act as a reminder to use the product. Therefore, it is a good idea to choose a time that is close to the time of expected product use. The time can be changed later on, if desired by the participant.
- 4) The participant should respond to an SMS daily immediately after receiving it during the eight-weeks that he/she is using the study product. S/he will receive the daily reminder at the pre-determined, programmed time. Inform the participant that if he/she does not receive the daily SMS for any reason, he/she may still report product use by sending an SMS to the system access number with his/her password, which will prompt the system to respond by asking about product use.
- 5) Let the participant know that you will contact him/her if s/he has not sent any SMS text messages for 48 consecutive hours, in order to make sure that s/he is not having problems with the SMS system.
- 6) Instruct the participant to be as honest as possible when answering the questions via SMS. His/her responses will help to develop a product that will be useful to people like him/her.
- 7) Alert the participant that the SMS should not be used for reporting to the clinic staff any medical problems that may result from study gel use or study tablet taking. If the participant has any medical problems such as burning, irritation, diarrhea, nausea etc., he/she should contact the clinic staff.
- 8) Give the participant the SMS Instruction Card (available at <http://www.mtnstopshiv.org/node/4524>) and fill in:
 - ✓ the participant's SMS password,
 - ✓ the SMS access number (varies by country),
 - ✓ compensation amount per completed reporting session/day,
 - ✓ bonus amount if miss fewer than 4 days per month,
 - ✓ site contact information, and
 - ✓ reminder time
- 9) Participants will need to join the system at each Initiate Period Visit by sending a text message from their cell phone that states "Join [SMS Password] [Reminder time]"

(i.e., Join BS1 2300).” They will not receive the daily SMS during each washout period. Please refer to the training script available on the MTN-017 web page under Study Implementation Materials for more details.

- 10) Participants will need to alert the SMS system to stop reminders at each End Period Visit by sending a text message from their cell phone that states “STOP.” This text message should be sent by participant in the presence of the study coordinator at each End Period Visit.
- 11) If product is permanently discontinued, study staff should instruct participants to send a text message that states “STOP” to the SMS system at the visit in which product is discontinued, so that they will not continue to receive reminders while they are not using the product.

6.7.2.5 SMS Diary Troubleshooting

If you encounter any problems with the SMS Diary, notify the team by sending an email to mtn017sms@mtnstopshiv.org. The team of staff members at Columbia University (William Brown III and Rebecca Giguere) will be available to assist you in troubleshooting and resolving any problems you may have with the SMS Diary. 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, date and time of when the problem occurred, and the password and phone number that was used, if available.

6.7.3 In-depth Interview

6.7.3.1 In-depth Interview Description

At the end of the first 8-week cycle, a subsample of approximately 40 participants will be selected to participate in phone interviews remotely held by bilingual interviewers. Participants will be selected so as to have similar representation by country and study regimen.. The purpose of these interviews is to gain in-depth knowledge of the factors, across cultures that may facilitate or detract from adherence to product use and trial procedures, as well as opinions on product acceptability. The interview will follow an interview guide and will be audio-recorded and transcribed.

6.7.3.2 In-depth Interview Preparation

Two weeks before Visit 4, the BRWG will inform site staff via email if the participant has been selected for the In-depth Interview. These participants will be selected based on their consent to be interviewed and their adherence rates as indicated by the SMS Diary. They should be informed that they have been selected for the interview, will receive the extra compensation, and should allot an extra 30 minutes for the interview during Visit 4. If possible, please keep in mind the time difference when scheduling appointments for participants to be interviewed (i.e., try to set the appointment at a reasonable hour for both the participant and the interviewer based in New York). Please email Rebecca Giguere (Giguere@nyspi.columbia.edu) to alert the BRWG of the time set for the Visit 4 appointment and the expected time at which the participant will be available for the interview. You will receive a confirmation email from the interviewer that confirms the appointment and informs you of the contact information for the interviewer. Please provide the interviewer with a phone number where she/he can reach you for the interview.

6.7.3.3 In-depth Interview Equipment

Each study site will have a landline telephone for participants to use for the In-depth Interview. Sites should select a location in the research offices for the interview that is private (i.e., participants cannot be easily overheard) and quiet, without a lot of background noise.

6.7.3.4 In-depth Interview Procedures

When the participant is ready for the interview, alert the interviewer via email or text message. The interviewer will call you at the phone number you provided via email. Once a secure

connection is established, pass the phone to the participant. Leave the room and tell the participant to alert you once the interview has finished. The interviewer will send an email confirming that the participant successfully completed the interview.

6.7.3.5 In-depth Interview Troubleshooting

If the participant announces that he/she will arrive late or will need to change his/her Visit 4 appointment, please notify the interviewer as soon as possible. If you are having any problems reaching the interviewer by phone, please send an email or text message to the interviewer.

Table 6-2

Timing of CASI Questionnaires, SMS Diary and In-Depth Interview (subset)

Study Visit	Behavioral Measures
Visit 2 , Enrollment, Initiate Period 1	Baseline Behavioral Questionnaire (CASI)
Visit 2 , Enrollment, Initiate Period 1 Visit 5 , Initiate Period 2 Visit 8 , Initiate Period 3	Initiate SMS Diary
Visit 4 , End Period 1	In-depth Phone Interview (subset)
Visit 4 , End Period 1 Visit 7 , End Period 2 Visit 10 , End Period 3	Follow-up Behavioral Questionnaires (CASI)

6.7.4 Data Convergence Interviews

6.7.4.1 Data Convergence Interview Description

At the Mid-period and End-period visits, adherence data on self-reported product use sent through SMS, and calculated product use via unused applicator/tablet returns will be recorded on a Data Convergence (non-DataFax) CRF that will be made available to the site counselor. See Section 6.7.2 for information on accessing the SMS data. Calculated product use data via the unused applicator/tablet returns is documented on the Product Dispensation and Return CRF. See the instructions on the back of the Data Convergence Interview (non-DataFax) CRF for specific details on form completion, including transcription of the SMS and product count data.

At each Mid-period and End-period visit, the site counselor will review with the participant the data from two measures (SMS and product count estimates of adherence), and will explore with the participant which of the two s/he believes yielded the most accurate report of the participant's true product adherence. The site counselor will interview the participant, using a non-judgmental approach, to elicit information about possible discrepancies (for more information, see Section 6.6). If no discrepancy is noted, the site counselor will interview the participant to verify whether the SMS and product count data is correct. Based on discussion with the participant, the counselor will determine a most likely adherence value (i.e., number of doses used in the past 4-week period in the opinion of the site counselor, based on the interview discussion). The counselor will record this value on the Data Convergence (non-DataFax) CRF, along with comments, based on the conversation with the participant, indicating reasons for this conclusion.

The Data Convergence Interview and Adherence Counseling sessions will be audio-recorded for quality control. After each interview, audio files will be uploaded to SCHARP's Atlas website for review by the BRWG. See section 'Post-interview Data Entry and Audio File Upload' for further details.

If the participant misses a Mid-period or End-period visit, the Data Convergence Interview should be made up at the participant's next regularly scheduled visit. The interview should focus on the study product regimen the participant last used (i.e., for which s/he was last dispensed study product). If the participant did not use any study product since the last regularly scheduled visit due to a clinical product hold/discontinuation, the Data Convergence Interview will be omitted; site staff will still need to complete the Data Convergence Interview CRF. Completion of the Data Convergence Interview CRF is required at all Mid-period and End-period visits, regardless of whether or not the data convergence interview was actually done. If the interview is not done, complete items 1-5, mark item 6 "no, specify" and document the reason the interview was not done on the adjacent line. If the Mid-period or End-period visit was missed in its entirety, a Data Convergence Interview form is not required. (See Data Communiqué #6 for more information, available at: <http://www.mtnstopshiv.org/node/4643>)

Table 6-3 below outlines the timing of each Data Convergence Interview as well as the reference data source.

6.7.4.2 PK Data Convergence Interview

At the End-period visits and Mid-period visits (when data are available), adherence data based on the results of PK data collected during the daily gel and daily oral regimens will be recorded on a PK Data Convergence (non-DataFax) CRF that will be made available to the site counselor. For visits in which BOTH Data Convergence and PK Data Convergence Interviews will be conducted, the PK Data Convergence Interview should be conducted AFTER the Data Convergence Interview. See the instructions on the back of the PK Data Convergence Interview (non-DataFax) CRF for specific details on form completion, including comparison of SMS and product count data.

At these visits, the counselor will review with the participant his/her real-time PK result and discuss the result in the context of a PK data convergence interview. During this interview, counselors will also reference the two additional data measures (SMS and product count estimates of adherence) from the visit in which the PK sample was collected to determine if there is a discrepancy between the PK result and the product return and/or SMS data. If a potential discrepancy is noted, the site counselor will interview the participant, using a non-judgmental approach, to elicit information about the possible discrepancies. The counselor will have on-hand a calendar of the SMS responses sent during that period to help the participant remember his/her reported use patterns. The calendar is available online via SCHARP's Atlas website, in the same folder as the SMS Data. To access the calendar, go to:

<https://atlas.scharp.org/cpas/project/MTN/017/Audio%20and%20SMS%20files/begin.view?>

After entering the Atlas website via the link and logging in, select your site name from the list on the left. Then scroll to the bottom of the page and select the folder labeled "SMS Files." You can then select the calendar for each participant at your site. The counselor will review the SMS entries starting with the most recent week of product use. The conversation with the participant will be documented on the PK Data Convergence (non-DataFax) CRF.

The PK Data Convergence Interview will be audio-recorded for quality control. After each interview, audio files will be uploaded to SCHARP's Atlas website for review by the BRWG. See section 'Post-interview Data Entry and Audio File Upload' for further details.

Table 6-3 below outlines the timing the each Data Convergence Interview as well as the reference data source.

Completion of the PK Data Convergence CRF is required at all End-period Visits (Visit codes 4.0, 7.0, and 10.0) and the second and third Mid-Period Visits (Visit codes 6.0 and 9.0), regardless of whether or not the PK Interview was actually done. If one of these visits is conducted but the interview is not done, indicate the reason in item 2 or 3 as appropriate. If one of these visits is missed in its entirety, a PK DCI form is not required. (See Data Communiqué #6 for more information, available at: <http://www.mtnstopshiv.org/node/4643>)

6.7.4.3 Data Convergence Interview Preparation

At the Mid-Period and End Period Visits, prior to the interview, site staff should complete items 1-2 on the PK Data Convergence Interview (non-DataFax) CRF and items 1-5 on the Data Convergence Interview (non-DataFax) CRF by transcribing the real-time PK test result, the estimated number of doses used based on unused product returns (tablets/applicators), and the estimated number of doses used based on the SMS data. See section 6.7.2 for information on accessing the SMS data.

6.7.4.4 Post-interview Data Entry and Audio File Upload

Within seven working days after the interview, a designated member of site staff will need to enter the data from the Data Convergence Interview (non-DataFax) CRF into a web-based form, which can be accessed on-line at www.scharp.org/MTN017/dc. Enter the data as follows:

- 1) Enter PTID (including hyphens)
- 2) Enter the password: MTN017
- 3) Re-enter PTID
- 4) Following the paper form, enter the visit date, daily oral period, daily gel period, or RAI-associated gel use period and follow the screens to enter the remaining data, including total number of tablets taken or applicators used based on product return and SMS, a summary of the conversation with the participant, and the most likely number of doses used. **Enter data exactly as it appears on the form.**
- 5) Exit the form by closing the browser window. Your data will be sent automatically to SCHARP.

Similarly, data from the PK Data Convergence Interview (non-DataFax) CRF will need to be entered into a web-based form within seven working days after the interview, accessible at www.scharp.org/MTN017/pk. Enter the data as follows:

- 1) Enter the PTID (including hyphens)
- 2) Enter the password: MTN017
- 3) Re-enter PTID
- 4) Following the paper form, enter the visit date, the visit code from the visit at which the PK sample was collected, the real-time PK test result, whether a PK data convergence interview was conducted, and a summary of the conversation with the participant. **Enter data exactly as it appears on the form.**
- 5) Exit the form by closing the browser window. Your data will be sent automatically to SCHARP.

The BRWG will review the data from both forms and provide the final converged rate (i.e. most likely number of doses taken based on review of the site data) for the given time period, which will be sent only to SCHARP for data analysis purposes.

To avoid creating duplicate electronic study records for the Data Convergence and PK Data Convergence CRFs, please do not begin the CASI survey until you are ready to complete the entire survey. Do not enter data convergence data for the same form over multiple days. Once form data entry begins, do not terminate the session until all of the given form's data is entered and submitted. Review Table 6-3 prior to starting a new web form for data entry to prevent the creation of incomplete records due to the wrong form being chosen at a given visit.

If the site discovers a transcription error on the Data Convergence Interview CRF and the interview has already been conducted using the incorrect information, do NOT correct the error on the Data Convergence Interview form. Instead, add an initialed and dated note to item 7 comments section to document the transcription error and explain what the correct value is. Enter the data into the web-based form exactly as it appears on the Data Convergence Interview CRF, entering each transcription error and a note in item 7. (For more information, see Data Communiqué #7, available at: <http://www.mtnstopshiv.org/node/4643>)

The audio files from the interviews will need to be uploaded to SCHARP's Atlas website (available at: <https://atlas.scharp.org/cpas/project/MTN/017/Audio%20and%20SMS%20files/begin.view?>). After entering the Atlas website via the link, select your site name from the list on the left. Then scroll to the bottom of the page and select the folder labeled "Audio Files." Double-click on the folder, and then press the button that says "Upload Files." Browse your computer for the file, double-click on the file, and then select "Upload." You should then see the file name in the list below, at which point you may log out of the system. Please label the audio file from each session according to the following format:
COUNSELORNAME_PTID_DDMMYYYY_VISIT#
For example: RGIGUERE_999-00001-8_29JUL2013_V1

6.7.4.5 Data Convergence Interview Equipment

Sites should select a location in the research offices for the interviews that is private and quiet. The adherence counselor will use the Data Convergence CRF, the PK Data Convergence CRF and the Participant Centered Product Adherence Counseling Manual to guide the discussion with the participant about adherence to product use. Sites will also need a digital audio recorder for recording the sessions, and a computer with Internet connection to complete the online Data Convergence and PK Data Convergence forms.

6.7.4.6 Data Convergence Interview Troubleshooting

In the case that SMS data needed for the Data Convergence Interview are not available online, please email mtn017sms@mtnstopshiv.org. If you have trouble while completing the online forms, contact mtn017webtrouble@mtnstopshiv.org. The MTN 017 Web Trouble team will assess the problem and communicate with you about resolutions.

Table 6-3

Data Convergence Interview Schedule & Components

Study Visits	Required Non-DataFax CRFs	Data Convergence Interview Discussion Points
PERIOD 1		
Week 4: Mid Period 1 <u>Visit 3</u>	Data Convergence Interview	<ul style="list-style-type: none"> SMS calendar data between Visit 2/Enrollment and Visit 3 Product count data at Visit 3
Week 8: End Period 1 <u>Visit 4</u>	Data Convergence Interview	<ul style="list-style-type: none"> SMS calendar data between Visit 3 and Visit 4 Product count data at Visit 4
	PK Data Convergence Interview*	<ul style="list-style-type: none"> PK result from blood collected at Visit 3 SMS and product count data as recorded on the Data Convergence Interview CRF completed at Visit 3 SMS calendar data between Visit 2/Enrollment and Visit 3
PERIOD 2		
Week 13: Mid -Period 2 <u>Visit 6</u>	Data Convergence Interview	<ul style="list-style-type: none"> SMS calendar data between Visit 5/Initiate Period 2 and Visit 6 Product count data at Visit 6
	PK Data Convergence Interview*	<ul style="list-style-type: none"> PK result from blood collected at Visit 4 SMS and product count data as recorded on the Data Convergence Interview CRF completed at Visit 4 SMS calendar data between Visits 3 and 4
Week 17: End Period 2 <u>Visit 7</u>	Data Convergence Interview	<ul style="list-style-type: none"> SMS calendar data between Visit 6 and Visit 7 Product count data at Visit 7
	PK Data Convergence Interview*	<ul style="list-style-type: none"> PK result from blood collected at Visit 6 SMS and product count data as recorded on the Data Convergence Interview CRF completed at Visit 6 SMS calendar data between Visits 5 and 6
PERIOD 3		
Week 22: Mid-period 3 <u>Visit 9</u>	Data Convergence Interview	<ul style="list-style-type: none"> SMS calendar data between Visit 8 and Visit 9 Product count data at Visit 9
	PK Data Convergence Interview*	<ul style="list-style-type: none"> PK result from blood collected at Visit 7 SMS and product count data as recorded on the Data Convergence Interview CRF completed at Visit 7 SMS calendar data between Visits 6 and 7
Week 26: End Period 3 <u>Visit 10**</u>	Data Convergence Interview	<ul style="list-style-type: none"> SMS calendar data between Visit 9 and Visit 10 Product count data at Visit 10
	PK Data Convergence Interview*	<ul style="list-style-type: none"> PK result from blood collected at Visit 9 SMS and product count data as recorded on the Data Convergence Interview CRF completed at Visit 9 SMS calendar data between Visits 8 and 9

* The PK Data Convergence Interview is conducted only if a PK result is available and only if the visit falls within the daily oral or daily rectal gel regimen periods. If the visit falls within the RAI-associated rectal gel period, the PK Data Convergence Interview CRF is still completed to document the PK result; however, the interview to converge the PK result with the SMS and product count data is omitted. If a PK result is not available at the time of the visit, the PK data convergence interview is omitted; however, the PK Data Convergence Interview CRF is still completed to document that no interview was done.

**At Visit 10, the PK Data Convergence Interview CRF is completed to document a PK result from blood collected at Visit 9, and to document the PK interview itself, if it was conducted. Once the PK result from the blood sample collected at Visit 10 is available, a second (new) PK Data Convergence Interview CRF should be completed to document the Visit 10 sample PK result.

Note: If a participant misses a visit at which a data convergence interview or PK data convergence interview was expected to take place, the missed interview(s) should be made up at the participant's next regularly scheduled visit.

6.8 Appendices

Section Appendix 1: Mock Participant ID's:

The following mock PTIDs will be used to practice completing the questionnaires and to troubleshoot any problems:

San Juan	Pittsburgh	Boston	Chiang Mai	San Francisco	Bangkok	Cape Town	Lima
999-00001-8	999-00016-4	999-00031-7	999-00046-0	999-00061-1	999-00076-8	999-00091-0	999-00106-7
999-00002-9	999-00017-0	999-00032-8	999-00047-1	999-00062-2	999-00077-9	999-00092-1	999-00107-8
999-00003-3	999-00018-8	999-00033-4	999-00048-7	999-00063-5	999-00078-4	999-00093-6	999-00108-0
999-00004-1	999-00019-6	999-00034-2	999-00049-5	999-00064-8	999-00079-2	999-00094-9	999-00109-3
999-00005-7	999-00020-8	999-00035-6	999-00050-2	999-00065-0	999-00080-3	999-00095-4	999-00110-7
999-00006-5	999-00021-4	999-00036-9	999-00051-5	999-00066-3	999-00081-9	999-00096-2	999-00111-0
999-00007-6	999-00022-0	999-00037-5	999-00052-6	999-00067-4	999-00082-5	999-00097-3	999-00112-1
999-00008-2	999-00023-7	999-00038-3	999-00053-1	999-00068-9	999-00083-2	999-00098-5	999-00113-6
999-00009-0	999-00024-5	999-00039-1	999-00054-4	999-00069-7	999-00084-0	999-00099-8	999-00114-9
999-00010-5	999-00025-3	999-00040-9	999-00055-9	999-00070-1	999-00085-8	999-00100-2	999-00115-4
999-00011-2	999-00026-1	999-00041-3	999-00056-7	999-00071-6	999-00086-6	999-00101-5	999-00116-2
999-00012-3	999-00027-2	999-00042-4	999-00057-8	999-00072-7	999-00087-7	999-00102-6	999-00117-3
999-00013-9	999-00028-6	999-00043-8	999-00058-0	999-00073-0	999-00088-1	999-00103-1	999-00118-5
999-00014-7	999-00029-9	999-00044-6	999-00059-3	999-00074-3	999-00089-4	999-00104-4	999-00119-8
999-00015-1	999-00030-0	999-00045-2	999-00060-6	999-00075-5	999-00090-7	999-00105-9	999-00120-5

Section Appendix 2: SMS Test Passwords

The following SMS test passwords will be used for testing and troubleshooting the SMS system.

BANGKOK	BOSTON	CAPE TOWN	CHIANG MAI	LIMA	PITTSBURGH	SAN FRANCISCO	SAN JUAN
BKTTEST1	BSTEST1	CTTEST1	CMTEST1	LMTEST1	PTTEST1	SFTEST1	SJTEST1
BKTEST2	BSTEST2	CTTEST2	CMTEST2	LMTEST2	PTTEST2	SFTEST2	SJTEST2
BKTEST3	BSTEST3	CTTEST3	CMTEST3	LMTEST3	PTTEST3	SFTEST3	SJTEST3
BKTEST4	BSTEST4	CTTEST4	CMTEST4	LMTEST4	PTTEST4	SFTEST4	SJTEST4
BKTEST5	BSTEST5	CTTEST5	CMTEST5	LMTEST5	PTTEST5	SFTEST5	SJTEST5
BKTEST6	BSTEST6	CTTEST6	CMTEST6	LMTEST6	PTTEST6	SFTEST6	SJTEST6
BKTEST7	BSTEST7	CTTEST7	CMTEST7	LMTEST7	PTTEST7	SFTEST7	SJTEST7
BKTEST8	BSTEST8	CTTEST8	CMTEST8	LMTEST8	PTTEST8	SFTEST8	SJTEST8
BKTEST9	BSTEST9	CTTEST9	CMTEST9	LMTEST9	PTTEST9	SFTEST9	SJTEST9
BKTEST10	BSTEST10	CTTEST10	CMTEST10	LMTEST10	PTTEST10	SFTEST10	SJTEST10