

## Section 7. Study Product Considerations for Non-Pharmacy Staff

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This section provides information and instructions for non-pharmacy staff related to the ordering, transport, delivery and administration of MTN-014 study product for study participants. Associated instructions for pharmacy staff are provided in the MTN-014 Pharmacist Study Product Management Procedures Manual, which will be made available to the site Pharmacist of Record (PoR) by the MTN LOC Pharmacist.

### 7.1 Study Product Regimens

Each study participant is expected to complete two study product regimens with tenofovir (TFV) reduced glycerin (RG) 1% gel: once-daily rectal administration and once-daily vaginal administration.

The order in which study participants will complete the two regimens will be based on her randomization assignment to one of two regimen sequences (Sequences A or B). Each sequence will consist of two 14-day periods of study product administration. A six-week washout period will occur between the two study product periods.

**Figure 7-1 Study Regimen Sequences**

	N	Period 1: 2 Weeks	Washout: ~6 Weeks	Period 2: 2 Weeks	Dose and Frequency
<b>Sequence A</b>	7	Vaginal		Rectal	Entire contents of a single applicator will be inserted daily
<b>Sequence B</b>	7	Rectal		Vaginal	Entire contents of a single applicator will be inserted daily

As shown in Figure 7-1, study participants will be randomly assigned in equal numbers to one of two study sequence regimens.

### 7.2 Study Product Use Instructions

#### 7.2.1 Vaginal Administration

During the vaginal use period of the study product, participants will undergo daily directly observed dosing in the clinic. Participants will be instructed to insert one pre-filled applicator of gel into the vagina daily for the two-week study period, as close to the same time each day as possible.

During the Initiate Period Visit for the vaginal use period, the participant will be given two doses of gel to use at home in the rare event that she is unable to come to the clinic. If a participant is not able to come to the clinic for directly observed vaginal dosing, the participant must insert vaginally the dose without observation as close to the scheduled time of the directly observed dose, unless the next dose is estimated to be due within six hours. If the next dose is estimated to be due within six hours, the dose should be skipped. The next dose will be inserted into the vagina as originally scheduled.

Vaginal use instructions may be found on the MTN-014 Study Implementation website <http://www.mtnstopshiv.org/node/4665>). A list of frequently asked questions pertaining to vaginal administration is available in Appendix 7-1.

### **7.2.2 Rectal Administration**

During the rectal use period of the study product, participants will undergo daily directly observed dosing in the clinic. Participants will be instructed to insert one pre-filled applicator of gel into the rectum daily for the two-week study period, as close to the same time each day as possible. Clinic staff will instruct the participant to use a small amount of the study-provided lubricant on the outside of the applicator for ease of rectal insertion. The clinic will maintain a supply of the lubricant (4 mL packets), which will be provided by the MTN LOC pharmacist. One packet should be given for each applicator for rectal use. The clinic will also receive 4 oz. tubes of the lubricant for use during study-related procedures.

During the Initiate Period Visit for the rectal use period, the participant will be given two doses of gel (and two packets of lubricant) to use at home in the rare event that she is unable to come to the clinic. If a participant is not able to come to the clinic for a directly observed rectal dosing, the participant must insert rectally the dose without observation as close to the scheduled time of the directly observed dose, unless the next dose is estimated to be due within six hours. If the next dose is estimated to be due within six hours, the dose should be skipped. The next dose will be inserted into the rectum as originally scheduled.

Detailed instructions for rectal gel insertion are found on the MTN-014 Study Implementation website <http://www.mtnstopshiv.org/node/4665>). A list of frequently asked questions pertaining to rectal administration is available in Appendix 7-1.

### **7.3 Prescriptions and Dispensing Study Products at Initiate Period Visits**

The statistical data management center (SDMC) will generate and maintain the study randomization scheme which determines the study product regimen sequence assigned to each participant. The randomization envelopes will be sent by the SDMC to the site clinic. The MTN Pharmacist will provide site clinic staff with study prescription forms (See Appendix 7-2).

Study products will be dispensed by the pharmacist to enrolled participants or to study staff on behalf of the participant, upon receipt of an original, written study prescription that is signed by an authorized prescriber. The CRS name and DAIDS Site ID will be pre-printed on the study prescription. Clinic staff must record on the study prescription the PTID, and randomization envelope number, and check the box indicating the study sequence and the study period for the given participant. Study prescriptions will be produced as two-part no carbon required (NCR) sheets. The top white form is the original (pharmacy), and the bottom form is the copy (clinic). Once a study prescription is completed and signed by an authorized prescriber at the site, clinic staff will separate the two sheets of the form and the white original will be delivered to the site pharmacy. The yellow copy will be retained in the participant's study notebook in the site clinic. Corrections to the study prescriptions should only be made by study staff authorized to complete the original prescription. The same corrections should be made separately on both the original white sheet and the yellow copy. A signed and dated note explaining the corrections if needed also should be recorded on both sheets. Identical corrections and notes should be recorded on both copies, on the same date, by the same person.

One prescription must be completed at each of the two Initiate Period Visits (Visit 2 and Visit 18). The pharmacist will dispense 3 prefilled applicators at the initiate visit for the daily vaginal administration period and 3 prefilled applicators at the initiate visit for the daily rectal use period. One applicator is for administration at that visit for directly observed dosing in the clinic, and two applicators are for as-needed home dosing by the participant.

#### **7.4 Study Product Request Slip – Study Product Re-Supply**

The MTN-014 Study Product Request Slip (Appendix 7-3) is used by clinic staff to communicate to the study pharmacist the quantity of study product to be re-supplied for daily directly observed clinic dosing and if additional as-needed home doses are required by the participant (i.e., cannot attend >2 clinic visits, product is lost, stolen or unusable for any reason) during either study product use period.

The slip will be produced as two-part no carbon required (NCR) sheets. The top white form is the original (pharmacy), and the bottom form is the copy (clinic). Bulk supplies of the slips are available from the MTN LOC Pharmacist and will be supplied to clinic staff throughout the course of the study. Clinic staff will complete the PTID, randomization envelope number, visit number and indicate the study product regimen on the top of the form. The clinic staff name, signature, and signature date must be completed by a clinic staff member authorized to order study product for participants during follow-up. Clinic staff comments may also be provided if needed.

Double-check the accuracy of all entries and then separate the two parts of the completed slip. Retain the yellow copy in the participant study notebook and deliver the white original to the pharmacy. If corrections are needed, the same corrections must be made separately on both the white original sheet and the yellow copy. A signed and dated note explaining the corrections also should be recorded on both sheets. Identical corrections and notes should be recorded on both copies, on the same date, by the same person.

#### **7.5 Study Product Management Slip**

The Study Product Management Slip (Appendix 7-4) is provided to the research site staff by the MTN LOC Pharmacist and is completed by the research clinic staff. It is to be used by the clinic staff to formally communicate to the site pharmacy when there is a product hold, resume, permanent discontinuation, participant decline, or if a participant is no longer in the study.

The request slip is a two part NCR paper document. The top white is the original (pharmacy) and the bottom is yellow (clinic copy). Retain the yellow copy in the participant study notebook and deliver the white original to the pharmacy. If corrections are needed, the same corrections must be made separately on both the white original sheet and the yellow copy. A signed and dated note explaining the corrections also should be recorded on both sheets. Identical corrections and notes should be recorded on both copies, on the same date, by the same person.

### **7.5.1 Product Hold/Resume**

If a study clinician determines that a participant should temporarily hold study product use due to safety reason(s) (e.g., an adverse event), mark the “HOLD” box on the MTN-014 Study Product Management Slip (Appendix 7-4). Record the reason for the hold on the adjacent “Reason” line. It is not necessary to complete any new slips at subsequent visits in which the hold is still in effect. Once a product hold is in effect, the site pharmacist will not dispense any study product to that participant until he/she receives a management slip from the site clinic marked “RESUME”. Only clinic staff members who are authorized prescribers may mark the “RESUME” box. In all other circumstances, the slips are not required to be signed by an authorized prescriber; however site-specific pharmacy regulations may be more stringent than these requirements. All sites must comply with local requirements. The “RESUME” box should only be checked if study product is being ordered and dispensed following a product hold.

### **7.5.2 Permanent Discontinuation of Study Product**

If a study clinician determines that a participant should permanently discontinue study product use due to safety reason(s) (e.g., HIV infection), mark the “PERMANENT DISCONTINUATION” box. Record the reason for the permanent discontinuation on the “Reason” line provided. Once a permanent discontinuation is in effect, the site pharmacist will not dispense any further study product to that participant. Future slips will no longer be completed at the participant’s remaining study visits.

### **7.5.3 Participant-Initiated Decline of Study Product**

If a participant decides on her own to stop using study product, and refuses to be re-supplied further study product, do not mark the “HOLD” box. Instead, mark the “PARTICIPANT DECLINE” box on MTN-014 Study Product Management Slip. Complete the slip and mark “PARTICIPANT DECLINE” at each subsequent visit that the participant refuses study product. If the participant changes her mind and later decides to restart study product use, complete the MTN-014 Study Product Request Slip and mark “RE-SUPPLY”.

### **7.5.4 Scheduled and Early Terminations**

When a participant has completed her study participation, whether a scheduled or early termination, mark the “PRODUCT USE PERIODS COMPLETED” box on the slip. This serves as a notification to the site pharmacist that the participant will no longer be requiring any additional study product dispensations.

## **7.6 Chain of Custody**

Study product will be dispensed to an individual participant from the pharmacy to an authorized clinic staff member who will then deliver the applicator(s) to the participant. The site must designate its Chain of Custody (dispensing method) for study product in MTN-014 standard operating procedures (SOPs) for product dispensing and re-supply during MTN-014 follow-up. These SOPs should be developed with input from both pharmacy and clinic staff. They must be approved by the MTN Pharmacist prior to study activation and may only be modified after consultation with the MTN Pharmacist.

### **7.6.1 Dispensing from the Pharmacy to Clinic Staff**

To dispense study product to clinic staff who will then deliver the product to participants, prescriptions, study product request slips, and study product management slips are expected to be delivered to the pharmacy by clinic staff or a runner. Upon receipt of a correctly completed and signed prescription, study product request slip, or study product management slip, the PoR will prepare the requested quantity of study product as documented on the prescription or slip.

The MTN-014 Record of Receipt of Participant-Specific Study Gel (Appendix 7-5) must be used to document dispensing of study product to clinic staff for a given participant. For each Record of Receipt, pharmacy staff will complete the top section (CRS name, DAIDS site ID number, Product Lot, and PTID) and the first three columns in the body of the record. When receiving study product from the pharmacy for a given participant, clinic staff will verify and record the PTID in the designated column, confirm the quantity of study product dispensed, as documented by the site pharmacist, and complete the remaining three columns in the body of the record. Comments may be recorded in the designated column and, if additional space is needed, on the back of the record. All Records of Receipt will be retained in the site pharmacy.

Clinic staff are responsible for controlling access to the study products dispensed into their custody and ensuring that the products are delivered to the participants for whom they were dispensed. Clinic staff also must document delivery of the study products to the designated participants in the participants’ study charts. Delivery may be documented in chart notes or on other source documents used for this purpose. In the event that all study products dispensed for a participant are not delivered to the participant, clinic staff will document this in the participant’s study chart and return the study products to the pharmacy as soon as the participant’s visit is completed or as soon as it is known that the participant will not be completing her study visit on the scheduled date.

## **7.7 Unused Study Product Return and Retrieval**

Clinic staff will instruct each participant to bring all of her unused study product to the last study product administration visit for the specified study product administration period and at the early termination visit, if applicable. For example, the last study product administration visit for Period 1 is Visit 15, and the last study product administration visit for Period 2 is Visit 31. If participants do not return unused study product at Visit 15 and Visit 31, then they will be instructed to return used product to the clinic at Period 1 End Visit (Visit 16) and Period 2 End Visit/Final Clinic Visit (Visit 32). Clinic staff will collect the unused applicators and return them to the pharmacy.

The MTN-014 Record of Return (Appendix 7-6) must be used to document unused study product returns by clinic staff from each study participant to the pharmacy. Pharmacy staff will complete the top section (CRS name, DAIDS Site ID, study product lot number, and PTID). The clinic staff will complete the first three columns on the Record of Return. When receiving the returned study product at the pharmacy, pharmacy staff will verify the participant ID (PTID). For each PTID, they will then confirm the number of study product returned and complete the remaining columns on the Record of Returns. Comments may be recorded in the designated space, and, if additional space is needed, on the back of the record. All Records of Return will be retained in the pharmacy. Once the returned unused study product is received at the site pharmacy, it will be designated for quarantine and destruction. In MTN-014, unused study product that is returned by participants will not be re-issued.

Due to the duration of product use (14 days per period) and quantity dispensed for home use (2 applicators per period unless more applicators are required), the need for product retrieval is expected to be rare. When product retrieval is required, retrieval may occur by the participant returning the study product to study staff (at a time other than a regularly scheduled study visit).

Participants will be instructed to return all unused study product back to the site at the study visits listed above. If the participant does not return the unused study product, attempts to retrieve the unused product should be documented. Refer to protocol section 6.4.5 for requirements on study product return and retrieval in the event of a study product hold or permanent discontinuation. If the product is not retrieved within seven working days, clinic staff must inform the Protocol Safety Review Team (PSRT).

**Appendix 7-1**  
**Product Use Frequently Asked Questions**

1. What is the best position to insert the gel vaginally?

A: Find the position that feels most comfortable to you. Many people already have a position they prefer (kneeling, squatting, etc.). If you do not have a preferred position, we recommend that you lie on your left side or on your back.

2. What is the best position to insert the gel rectally?

A: Find the position that feels the most comfortable to you. Many people may already have a position that they prefer. If you do not have a preferred position, we recommend that you stand or lie on your side to insert the gel rectally.

3. What should I do if it hurts when I use the applicator to insert the gel?

A: Inserting the gel should not be painful. If you have pain when inserting the gel vaginally, try another position (sitting, standing, or lying down). If you still have pain in the new position, perhaps you need to change the angle of the applicator. The applicator should be angled slightly upward, towards your back, when you insert it. If you try to change the angle, and you still feel pain on insertion, please contact the study clinic.

If you are using the gel rectally, make sure there is lubricant on the outside of the applicator as inserting a dry applicator may cause discomfort. You should also not force the applicator into the rectum.

4. Where does the gel go to after I put it inside?

A: The study gel stays in the rectum or vagina. Some study gel will likely come out of the vagina over time. This is normal and expected. It is not likely that some of the gel will leak from the rectum. Sometimes when the gel comes out it looks clear. Sometimes it has a white color, and sometimes it has white clumps. This has been seen in other studies of the gels and it is normal. It is not normal to see a yellow or green discharge from the vagina or rectum, or a discharge with a bad odor, or with pain or itching. If this happens, it could mean you have an infection, in which case you should contact the study clinic.

5. Can the applicator get lost inside me?

A: No, the applicator cannot get lost inside you. When you use the applicator, hold it with your fingers about half-way along the barrel, and insert it until your fingers touch your body. Half of the barrel of the applicator should go inside your body. The other half should stay outside the body. Once the contents are inserted, remove the entire applicator and discard.

6. What should I do if I have trouble applying the gel with the applicator?

- A: The applicators should be easy to use, both vaginally and rectally. The applicator, when used rectally, should be slightly lubricated with the lubricant provided by the clinic staff. If you have difficulty using the applicators, ask study staff for help, as they may be able to show you different ways that you can insert the gel, which might make it easier.
7. What should I do if I think there is something wrong with an applicator?
- A: If there seems to be something wrong with an applicator (for example, you find it difficult to push the study gel out of the applicator, or if study gel has leaked out, or you think there is some other problem), do not use the applicator. Use another applicator instead. Keep the applicator that had something wrong with it and show it to staff or bring it to the study clinic at your next study visit. If you think that something is wrong with all of your applicators at home, contact the study staff as soon as possible (i.e., do not wait until your next visit) so the staff can make sure you have enough working applicators.
8. What happens if I press the plunger too early and most of the gel comes out on my outside? Can I put more in?
- A: If most of the study gel comes out on your outside, let study staff know and they will provide you with a new applicator to use. If you are at home, dispose of that applicator and use a new applicator to insert another dose of study gel. If this occurs with more than one applicator at home, contact the study staff as soon as possible (i.e., do not wait until your next visit) so the staff can make sure you have enough working applicators.
9. How do I store the gel?
- A: Store the study gel in a safe, cool, dry place at room temperature and not in the sun and out of reach of children.
10. What happens if the applicators get wet before I use them?
- A: If only the wrapper gets wet, the applicator can still be used. Dry the wrapper off before taking out the applicator. If the applicator itself gets wet, it should not be used, but this might only happen if the wrapper is already open.
11. What should I do if the wrapper is already open when I want to use the gel?
- A: You should only use applicators with sealed wrappers, so you should always open the wrapper right before inserting the gel. If you notice an applicator with a wrapper that is not sealed, do not use that applicator and let the study staff know. If you are at home, use a different applicator with a sealed wrapper instead. Discard the applicator with the open wrapper. When you return for the next scheduled visit and you should inform the study staff of any applicators you had to discard because the wrapper was not sealed. If you find that more than one wrapper is not sealed, please contact the clinic immediately to discuss obtaining a resupply of study product.
12. What should I do if I forget to come to the clinic and use the gel?



- A: If you miss an appointment, you should call the clinic staff. If you aren't able to come into the clinic that day, you should insert the missed dose as soon as possible, unless the next dose is estimated to be due within 6 hours. If the next dose is estimated to be due within six hours, you should skip the missed dose. The next dose should be inserted as originally scheduled.
13. What should I do if I have a reaction to the study gel at home (e.g., unusual itching, stinging)?
- A. Contact the study staff and ask their advice. They might ask you to go to the clinic to be assessed and receive treatment, if needed.
14. Can I use the study gel before oral, anal or vaginal sex?
- A. There is no data regarding the safety of orally ingested gel. In addition the taste of the gel may be unpleasant. If possible avoid gel use immediately prior to oral sex. The gel may be inserted safely prior to vaginal or anal sex. However, participants must abstain from vaginal and rectal intercourse 72 hours prior to and following the collection of samples.
15. Does it matter what brand of condoms we use?
- A. Ideally, you should only use the condoms given to you by the study clinic staff. However, if you do not have one of those condoms, and you have a different condom, use that condom. If a condom other than the condoms given to you by the study clinic staff is used, inform the study clinic staff of the change. It is always important to use condoms that do not have nonoxynol 9 (N9) lubricant, as this may cause some damage to cells in the vagina and in the rectum which could increase your chances of acquiring HIV and other sexually transmitted infections (STIs). Condoms are the only known way to protect against HIV and other (STIs), so it is always better to use any condom (even if it was not given to you by the study) than to use no condom.
16. What should I do if the gel leaks out?
- A: It is likely that some gel will leak out. This is normal and you don't need to do anything about it. You should always apply the full amount contained in the applicator. It may be helpful to wipe yourself on the outside with a dry cloth/tissue if you have been standing for a minute or two after you applied the gel, if you find that a small amount leaks out. The study staff will give you panty liners to help catch the gel if it leaks out.
17. Can I use tampons at the same time as the gel?
- A: You should not use tampons during study gel dosing periods, or 24 hours prior to period initiation and period end visits. If you happen to be on your menses during your gel use period, you should use a panty liner, a pad or sanitary napkin if you are able. If you are not able to use a panty liner, a pad or sanitary napkin, and have to use tampons, please notify clinic staff at your next appointment.

**Appendix 7-2  
MTN-014 Gel Prescription**

**MTN-014  
TENOFIVIR REDUCED GLYCERIN 1% GEL**

**Instructions:** All entries must be made in blue or black ink. Press firmly when completing this form. Corrections may be made by drawing a line through incorrect entries, recording correct information, and initialing and dating the correction.

<b>CRS Name:</b>	<pre-printed>		
<b>DAIDS Site ID:</b>	<pre-printed>	<b>Randomization Envelope #:</b>	

**Participant ID:**        -       -

**Study Regimen Sequence:**  
(check one)

<input type="checkbox"/> <b>A</b>	<b>Period 1</b> Vaginal	<b>Period 2</b> Rectal
<input type="checkbox"/> <b>B</b>	Rectal	Vaginal

**Study Product Administration Period:**  
(check one)

<input type="checkbox"/>	Study Period 1 ( <b>Visit 2</b> )
<input type="checkbox"/>	Study Period 2 ( <b>Visit 18</b> )

**Tenofovir Reduced Glycerin 1% Gel**

**Sig:** Insert entire contents of one (1) applicator into rectum or vagina as directed.

**Quantity:** Sufficient to last for one 14-day study product administration period as specified above. Study product may be refilled as needed for the duration of the study product administration period.

Authorized Prescriber Name (please print): \_\_\_\_\_

Authorized Prescriber Signature: \_\_\_\_\_

Date:   -     -    
*dd                      MMM                      yy*

**Clinic Staff Instruction:** Once the prescription is completed, deliver white original (labeled "Pharmacy") to pharmacy. File yellow copy (labeled "Clinic") in participant's study notebook.

**Pharmacy:** Dispense 16 pre-filled tenofovir reduced glycerin 1% gel applicators.

- 3 applicators will be dispensed on Visit 2 (Initiate Study Period 1) or on Visit 18 (Initiate Study Period 2): 1 applicator is for direct observed dosing in the clinic and 2 applicators are for as-needed home dosing by the participant.
- One of the remaining 13 applicators will be dispensed daily for the remainder of the direct observed dosing study product administration visits (Study Period 1 Visits 3-15 or Study Period 2 Visits 19-31).

**Appendix 7-3**  
**MTN-014 Study Product Request Slip**

**Clinic Staff Instructions:** Once slip is completed, deliver white original (labeled “Pharmacy”) to the pharmacy. File yellow copy (labeled “Clinic”) in the participant’s study notebook.

<b>Participant ID</b> [ ] [ ] [ ] - [ ] [ ] [ ] [ ] [ ] - [ ]	<b>Randomization Envelope Number</b> [ ] [ ] [ ]
<b>Study Product Regimen:</b> Vaginal or Rectal <i>(circle one)</i>	<b>Visit #:</b> _____
<input type="checkbox"/> <b>RE-SUPPLY</b> $\longrightarrow$ <b>Pharmacy: Dispense</b> <input type="checkbox"/> 1 MTN-014 Pre-filled Applicator for clinic observed dosing <input type="checkbox"/> _____ MTN-014 Pre-filled applicator(s) <i>(specify quantity)</i> <b>Reason &gt; 1 applicator requested:</b> _____ _____	
<b>Clinic Staff Comments:</b>  	

Clinic Staff Name *(please print)*: \_\_\_\_\_

Clinic Staff Signature: \_\_\_\_\_

Date: [ ] [ ] - [ ] [ ] [ ] - [ ] [ ]  
          *dd*                      *MMM*                      *yy*

**Appendix 7-4  
MTN-014 Study Product Management Slip**

**Clinic Staff Instructions:** Mark the box that corresponds to the appropriate pharmacy action being requested. If ordering product after a hold, the "RESUME" box must be marked. For "RESUME" indicate the quantity of gel applicators to dispense. Once slip is completed, deliver white original (labeled "Pharmacy") to the pharmacy. File yellow copy (labeled "Clinic") in the participant's study notebook.

<b>Participant ID</b> <div style="display: flex; justify-content: space-between; align-items: center;"> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <span style="font-size: 20px; margin: 0 5px;">-</span> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <span style="font-size: 20px; margin: 0 5px;">-</span> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> </div>	<b>Randomization Envelope Number</b> <div style="display: flex; justify-content: space-around; align-items: center;"> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> <div style="border: 1px solid black; width: 20px; height: 20px; display: inline-block;"></div> </div>
<b>Study Product Regimen:</b> Vaginal or Rectal <i>(circle one)</i> <b>Visit #:</b> _____	
<input type="checkbox"/> <b>HOLD</b> → <b>Reason:</b> _____	
<b>Pharmacy:</b> Do not dispense further MTN-014 pre-filled applicators to the participant until another MTN-014 Study Product Management Slip marked "RESUME" with authorized prescriber signature is received.	
<input type="checkbox"/> <b>RESUME</b> → <b>Pharmacy: Dispense</b> <div style="margin-left: 40px;"> <input type="checkbox"/> 1 MTN-014 Pre-filled Applicator for clinic observed dosing  <input type="checkbox"/> _____ MTN-014 Pre-filled applicator(s) <i>(specify quantity)</i>  <b>Reason &gt; 1 applicator requested:</b> _____            _____         </div>	
<input type="checkbox"/> <b>PERMANENT DISCONTINUATION</b> → <b>Reason:</b> _____	
<b>Pharmacy: Do not dispense</b> any further MTN-014 study product to this participant.	
<input type="checkbox"/> <b>PARTICIPANT DECLINE</b> → <b>Pharmacy: Do not dispense</b> – participant is <b>refusing study product</b> .	
<input type="checkbox"/> <b>PRODUCT USE PERIODS COMPLETED</b> → <b>Pharmacy: Do not dispense</b> any further MTN-014 study product to this participant.	

Clinic Staff Name *(please print)*: \_\_\_\_\_

Clinic Staff Signature: \_\_\_\_\_

Date: 

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*dd*
*MMM*
*yy*

**Appendix 7-5**  
**Record of Receipt of Participant-Specific Study Gel**

<b>DAIDS Site ID:</b>	<b>CRS Name:</b>
<b>Product Lot:</b>	<b>PTID:</b>

PHARMACY STAFF			CLINIC STAFF/COURIER/RUNNER/PARTICIPANT			
Date and Time Dispensed by Pharmacy dd-mm-yy (hh:mm) 24 hr clock	Number of Gel Applicators Dispensed by Pharmacy	RPh Initials	PTID (Verify PTID)	Date and Time Received from Pharmacy dd-mm-yy (hh:mm) 24 hr clock	Clinic Staff/ Courier/ Runner/ Ppt Initials	Comments

Instructions: Complete one row each time study product is dispensed from the pharmacy. All entries must be made in dark ink. Corrections may be made by drawing a single line through incorrect entries, entering correct information, and initialing and dating the correction.

**Appendix 7-6  
Record of Return of Participant-Specific Study Gel**

<b>DAIDS Site ID:</b>	<b>CRS Name:</b>
<b>Product Lot:</b>	<b>PTID:</b>

<b>CLINIC STAFF</b>			<b>PHARMACY STAFF</b>			
Date Returned by Participant dd-mm-yy (hh:mm) 24 hr clock	Number of Gel Applicators returned by Participant	Clinic Staff Initials	PTID (Verify PTID)	Date and Time Returned to Pharmacy dd-mm-yy (hh:mm) 24 hr clock	RPh Initials	Comments

Instructions: Complete one row each time study gel is returned by the participant to non-pharmacy staff for subsequent return to the site pharmacy. All entries must be made in dark ink. Corrections may be made by drawing a single line through incorrect entries, entering correct information, and initialing and dating the correction.