

MTN-017

FOLLOW-UP

Study Product Considerations

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Presentation Overview

- Study Product Request Slip
- Unused Study Product Return Slip



Product Dispensation: Follow-up Visits

- Clinic staff will request study product from the pharmacy by completing an **MTN-017 Study Product Request Slip** at:
 - Scheduled mid-period visits
 - Unscheduled interim visits, as needed



Product Dispensation: Follow-up Visits

- Transcribe from randomization document the **PTID** and **randomization envelope number on the MTN-017 Study Product Request Slip**.
- Request product:
 - 1 bottle of 30 tablets
 - 30 applicators
 - Specify quantity of applicators (up to 45 apps)

MTN-017 STUDY PRODUCT REQUEST SLIP

Participant ID:

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Randomization Envelope Number:

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 “RE-SUPPLY” and “RESUME” indicate the quantity to dispense of the appropriate study product (tablets or gel). Once slip is completed, deliver white original (labeled “Pharmacy”) to pharmacy. File yellow copy (labeled “Clinic”) in participant’s study notebook.

RE-SUPPLY —→ **Pharmacy Dispense**

Check One:

- 1 Bottle of Truvada Oral Tablets
 30 MTN-017 Prefilled Applicators
 ___ MTN-017 Prefilled Applicators (*specify quantity*)

HOLD —→ **Reason:** _____

Pharmacy: Do not dispense further MTN-017 study product to the participant until another MTN-017 Study Product Request Slip marked “RESUME” with authorized signature is received.

RESUME —→ **Pharmacy Dispense**

Check One:

- 1 Bottle of Truvada Oral Tablets
 30 MTN-017 Prefilled Applicators
 ___ MTN-017 Prefilled Applicators (*specify quantity*)

PERMANENT DISCONTINUATION —→ **Reason:** _____

Pharmacy: Do not dispense any further MTN-017 study product to this participant.

PARTICIPANT DECLINE —→ **Pharmacy: Do not dispense** - participant is refusing study product.

PARTICIPANT NO LONGER IN STUDY —→ **Pharmacy: Do not dispense** any further MTN-017 study product to this participant.

Clinic Staff Name (*please print*): _____

Clinic Staff Signature: _____

Date: --
dd MMM yy

Request Slip Completion

- This slip can be completed by any authorized clinic staff except in the case of indicating “RESUME”
 - Only authorized prescribers can indicate “RESUME”
- Double check the accuracy of all entries
- Errors may be corrected in blue or black ink by putting a line through and initialing
- Retain the yellow copy for the participant study notebook in the clinic
- Deliver white copy to pharmacy
- Once the white and yellow copies are separated errors must be corrected on each sheet separately

Request Slip Completion

□ RE-SUPPLY

- Used to by clinic staff to communicate to the pharmacist the study product quantity to be re-supplied to the participant at mid-period visits (both scheduled and unscheduled)
 - One bottle of Truvada tablets
 - 30 prefilled applicators or specify another quantity of applicators if damaged/stolen/lost/higher use (RAI period)



Request Slip Completion

□ HOLD

- Used by clinic staff to communicate to pharmacist that the participant has a temporary product hold due to a clinical/safety reason(s)
- Record reason for hold
- If hold > 7 days, retrieve study product within 7 working days

Request Slip Completion

□ RESUME

- Once a product hold is in effect, the pharmacist will not dispense any study product to that participant until a subsequent request slip is received, and “RESUME” is marked on that request slip
 - One bottle of Truvada tablets
 - 30 prefilled applicators or specify another quantity of applicators

Request Slip Completion

□ **PERMANENT DISCONTINUATION**

- If study clinician determines that a participant should permanently stop study product use due to safety reason(s), then the box for “PERMANENT DISCONTINUATION” is marked
- Indicate reason for permanent discontinuation
- Future study product requests slip will no longer be completed at the participant’s remaining study visits



Request Slip Completion

□ **PERMANENT DISCONTINUATION**

- Participants who are permanently discontinued are instructed to return all unused product to the site
- Following permanent discontinuation study product must be returned within 5 working days
- If it is not returned within 5 working days, clinic staff should document all efforts to have product returned
- Study product must be retrieved within 24 hours for HIV seroconversion or discontinuation due to Grade 3 or higher renal or hepatic toxicity



Request Slip Completion

□ PARTICIPANT DECLINE

- If a participant decides that they don't want to use the product then the box for "PARTICIPANT DECLINE" is marked
- This is not a clinical hold and does not require a "RESUME"
- When the participant wants to continue the product, the clinic staff will complete the request slip for "RE-SUPPLY"



Request Slip Completion

- **PARTICIPANT NO LONGER IN STUDY**
 - Used by clinic staff to communicate to the pharmacy when the participant has completed study product use or withdrawn from the study
 - Product must be returned within 5 working days after the Final Clinic Visit



Retrieval of Unused Product

- Guidelines in protocol section 6.4
- Study staff will conduct outreach to retrieve the unused product from the participant (e.g., at their home)
- Document efforts to retrieve unused study product
- If study product is not returned within the time frames outlined in the protocol, the PSRT must be notified

Unused Study Product Return

- Participants must return unused applicators and tablets at each **Mid-Period Visit** and **End-Period Visit**, **Early Termination** and **Final Clinic Visit**.
- Adherence data will be collected from the count of unused applicators and tablets returned.
- Clinic staff will complete the **MTN-017 Unused Product Returns Slip**.
- The appropriate information will be transcribed onto the MTN-017 Product Dispensation and Return CRF.



Unused Study Product Return

- Unused Study Product Return Slips were sent by SCHARP to the clinic and should be stored in the clinic.
- This form is used to document all unused study product returned at each visit.
 - This includes unused study product the participant is returning from the last visit's dispensation and any prior visits' dispensations.



Unused Product Returns Slip

- Complete the PTID and visit date on the MTN-017 Unused Study Product Returns Slip.
- If all study product returned was dispensed on the same date, complete only the first row.
- If there is study product returned from two different dispensation dates, complete one row for each date.



Unused Product Returns Slip

- If the participant is only returning one type of product, record zeros for the other type.
- If the participant did not return any product, complete the date of the last dispensation and zeros for the amount returned.
- Record any relevant information in the comments section.
- Insert clinic staff initials and date.



Unused Study Product Return

- ONLY unused study product should be returned to the pharmacy.
 - No used applicators should be returned.
- The pharmacy will document and quarantine any returned unused study product.
- If returning product because damaged or contaminated, record this information and any further details in the comments section.

MTN-017 UNUSED PRODUCT RETURNS

PTID: - -

VISIT DATE: ^{dd} - ^{MMM} - ^{yy}

Clinic Staff Instructions: Complete one MTN-017 Unused Product Returns Slip at each Mid-period and End-period/Final Clinic Visit, and any time a participant returns unused study product.

Document all unused study product that the participant returned at the visit. This includes study product that was dispensed at the last visit, and any unused study product that the participant is returning late (i.e., that was expected to be returned at a previous visit). If all returned product has the same dispensation date, complete the first row only. If the returned product is from different dispensations, complete one row for each dispensation date and record the amount returned from each dispensation. If the participant returned only one type of study product (tablets or gel), record zeros for the type of study product the participant did not return. If the participant did not return any unused study product, complete the first row only by recording the last date of dispensation and zeros for the amounts returned. Record any relevant information in the comments section.

<u>Date of Dispensation</u>	<u>FTC/TDF (Truvada)</u>		<u>Tenofovir RG 1% Gel</u>
<i>dd</i> <i>MMM</i> <i>yy</i>	# Bottles	# Tablets	# Unused Applicators
<input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/>	<input type="text"/>	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>
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Comments:

Clinic Staff Initials/Date: _____



Contact Information

- If you have any questions, please do not hesitate to contact us at:

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Thank You!

QUESTIONS