Section 6. Study Product Considerations for Non-Pharmacy Staff

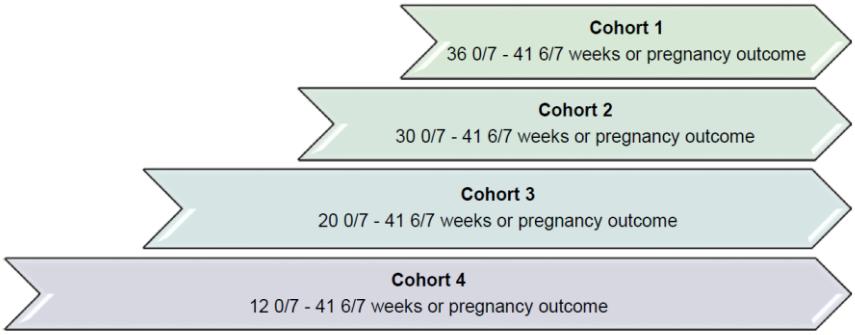
6. Introduction

This section provides information and instructions for non-pharmacy staff related to the ordering, transport, delivery and administration of MTN-042 study product for study participants. Only mother study participants will use study product in this study; all references to study participants in the section apply only to the mother. Associated instructions for pharmacy staff are provided in the MTN-042 Pharmacist Study Product Management Procedures Manual, which will be made available to each site Pharmacist of Record (PoR) by the MTN LOC Pharmacist.

6.1 Study Product Regimens

Mother participants within each Cohort (based on gestational age) will be randomized to one of two study products in a 2:1 ratio, either a VR containing 25 mg of dapivirine to be inserted monthly or Truvada® (200 mg FTC/300 mg TDF) one oral tablet taken daily. Participants will use their assigned study product until their pregnancy outcome but no later than 41 6/7 weeks of gestation, a maximum of approximately six (6) to thirty (30) weeks.

Table 6-1: Expected Maximum Duration of Product Use by Study Cohort



6.2 Randomization Assignment

The MTN SDMC will generate and maintain the study randomization scheme. Study participants will be randomly assigned 2:1 to the VR or tablets, respectively. Study product randomization will occur via the Medidata web-based system, as described in Section 11 (Data Collection) of this manual. After clinic staff has randomized a participant, they will need to view the participant randomization via Medidata to determine the assigned study product. The cohort and product assignment must be indicated on the prescription. Clinic staff complete a study prescription and send the original part to designated site pharmacy staff, as described in section 6.3 below, to notify the site pharmacist that the participant has been randomized and needs to be dispensed either a study VR or bottle of tablets.

6.3 Prescriptions and Dispensing Study Products

MTN-042 Prescriptions and Request Slips will be produced as two-part no carbon required (NCR) forms. MTN LOC Pharmacist will provide a bulk supply of the documents to the Pharmacist of Record (PoR) who will provide them to clinic staff throughout the course of the study.

Clinic staff will complete a study prescription (or request slip) and send the original (white) part to designated site pharmacy staff, as described below. The copy (yellow) is retained in the participant binder. If corrections are required on either the prescription or request slip, the same corrections must be made on both the white original prescription and the yellow copy. A signed and dated note explaining the corrections also should be recorded on both the white and yellow sheets. The same corrections and notes should be recorded on both the white original and yellow copy, on the same date, by the same person. Corrections to original study prescriptions should only be made by an authorized prescriber and fully documented in the participant's chart notes.

One prescription must be completed for each participant at their enrollment visit. Both the oral Truvada (FTC 200mg/TDF 300mg) tablet and the dapivirine 25mg VR are listed on the MTN-042 Prescription (Appendix 6-1). The prescription is sufficient to allow for product dispensing for the entire study. The prescription for the oral tablets and the VR indicates that the quantity dispensed at each visit will be sufficient to last until the next study visit. The pharmacist will dispense one bottle of 30 study tablets or one VR at enrollment and then monthly thereafter until the end of study product use.

6.3.1 In Clinic Prescription Procedures (C1-C5):

C1. After the participant is randomized, (i.e. the Randomization CRF is completed), complete an MTN-042 Prescription per instructions on the prescription. The person who marks the informed consent check box is responsible for confirming the presence of a properly signed/marked and dated informed consent form for enrollment prior to recording his/her initials beside these boxes.

C2. The box indicating the randomized cohort and study product must be checked.

C3. The bottom section of the prescription requires authorized prescriber name, signature, and date. This study staff member must be designated in the site's delegation of duties as an authorized

prescriber of study product. This person also must be listed as an investigator (either the Investigator of Record or Sub-Investigator) on the current FDA Form 1572.

C4. Double-check the accuracy of all entries and then separate the two parts of the completed prescription. Retain the yellow (clinic) copy in the participant study notebook.

C5. Deliver the white (pharmacy) original prescription to the study pharmacy.

6.3.2 In Pharmacy Prescription Procedures (P1-P2):

P1. Designated site pharmacy staff will receive a Medidata alert via email that a given participant was randomized by the site clinic staff. Specific product assignment is only visible to site clinic staff.

P2. Upon receiving the completed MTN-042 Prescription, the pharmacist will review the document for completion and accuracy. If a member of pharmacy staff identifies possible errors on the original prescription, he/she will return the original prescription to clinic staff for clarification(s) or correction(s).

P3. Following review of the signed MTN-042 Prescription, pharmacy staff will dispense the study VR or the Truvada tablets to clinic staff for participant use per instructions in the MTN-042 Pharmacy

Study Product Management Procedures Manual and in accordance with the site pharmacy SOP(s).

P4. The pharmacist will complete the Dispensing eCRF based on the prescription. If there is an error in the product requested the pharmacist will be informed. The error will be communicated with the clinic staff and the prescription will be corrected as indicated.

6.4 Study Product Request Slip

The MTN-042 Study Product Request Slip is used by clinic staff to communicate to the study pharmacist the study product and quantity to be re-supplied, as well as clinic staff decisions to hold, resume, or permanently discontinue study product use, or to indicate if the participant has terminated early from the study, is declining study product, or the study product use period is completed (Appendix 6-2).

Clinic staff will complete the Request Slip per instructions on the slip. When the form is used to request study product, 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. When the request slip is used to request product for “RESUME” after a hold is resolved, an authorized prescriber MUST sign the form. It is anticipated that “RESUME” is only indicated following a “HOLD”.

6.4.1 Study Product Re-Supply - Dispensing Study Products at follow-up Visits

The MTN-042 Study Product Request Slip (Appendix 6-2) will be used by clinic staff to communicate to the study pharmacist the study product (dapivirine VR or bottle of Truvada tablets) and the quantity to be re-supplied to each participant approximately every four weeks or as applicable. At visits, and any time additional product is needed (except to resume product use after a clinical product hold), mark the “RE-SUPPLY” box on the MTN-042 Study Product Request Slip. It is anticipated that when the request slip is used to resupply product at the scheduled follow-up visits, clinic staff will order a quantity of one VR or one bottle of 30 Truvada tablets. Clinic staff will indicate on the slip the type and amount of study product to be dispensed by indicating the quantity of Truvada tablet bottles or the quantity of dapivirine 25 mg VRs. However, if the participant is unable to attend her next scheduled visit, it is up to the discretion of the IoR/designee to allow the provision of additional study product. The reason for requesting >1 VR or bottle must be provided on the request slip. Oral Truvada tablets, however, must be ordered and dispensed only in bottles of 30 tablets. The IoR/designee will document approval of this additional dispensation on the request slip or the participant chart notes.

6.4.2 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-042 Study Product Request Slip. 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 new request 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 requested and dispensed following a product hold.

6.4.3 Participant-Initiated Decline of Study Product

If a participant decides on her own to stop using the study product, and refuses to be re-supplied further study product, do not mark the “HOLD” box on MTN-042 Study Product Request Slip. Instead, mark the “PARTICIPANT DECLINE” box. Complete the slip and mark “PARTICIPANT DECLINE” at each subsequent visit during the product use period (until pregnancy outcome) in which the participant refuses study product.

6.4.4 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., acquisition of HIV infection), mark the “PERMANENT DISCONTINUATION” box. If there is an early termination/withdrawal from the study before the end of product use, 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.

6.4.5 Product Use Period Complete

When the participant is ending study product use due to pregnancy loss/delivery, or if 41 6/7 weeks gestation has been reached, this box is checked and no further product will be dispensed.

6.5 Chain of Custody and Accountability

6.5.1 Dispensing from the Pharmacy to Clinic Staff

Study product will be dispensed from the pharmacy to an authorized clinic staff member who

will then deliver study product to the participant. Each study site must designate its Chain of Custody (dispensing method) for study product in MTN-042 SOPs for product dispensing and re-supply during MTN-042 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.

The pharmacist will dispense the study product to clinic staff who will then deliver the product to participants. Prescriptions and product request slips are expected to be delivered to the pharmacy by clinic staff or a runner or fax with original to follow. Upon receipt of a correctly completed and signed prescription or product request slip, the PoR will prepare the requested study product as documented on the prescription or request slip.

The MTN-042 Record of Receipt of Participant-Specific Study Product (Appendix 6-3) 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 PTID, assigned sequence, and the first four columns in the body of the record. When receiving study product from the pharmacy for a given participant, clinic staff will check to be sure the PTID and sequence are correct and confirm the study product and quantity of study product dispensed, as documented by the site pharmacist. Clinic staff will 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 should be documented on the Participant-Specific Clinic Study Product Accountability Log and in chart notes or on other source documents used for this purpose.

If study product dispensed for a participant is not delivered to the participant, clinic staff will document this on the log and in the participant's study chart and return the unused study products to the pharmacy as soon as the participant's visit is completed or as soon as clinic staff know that the participant will not be completing her study visit on the scheduled date.

6.5.2 Participant-Specific Clinic Study Product Accountability Log

This log (available on the MTN-042 website under Study Implementation Materials should be maintained and completed as outlined in the Clinic Study Product Accountability and Destruction SOP. The SOP should define who is responsible for updating this log, when it is updated, where it is stored, how and when it will be QC'd and who is responsible for the QC procedures. It must be updated at least daily and indicated in the Source Document SOP whether any of the data points will collect source data.

6.5.3 Off-Site Visits

Overall guidance on conducting off-site visits can be found in SSP Section 5.5.6. Sites choosing to deliver study product at off-site follow-up visits must specify product-related procedures for these visits in their Off-Site Visit SOPs for study product re-supply during follow-up. Since pharmacy staff will be required to dispense participant-specific study product for off-site visits before the visits take place, clinic staff will need to complete MTN-042 Study Product Request Slips for these participants in advance of the off-site visits. However, pharmacy staff will not release participant-specific study product to clinic staff who conduct off-site visits until immediately prior to their departure from the study site to perform these visits. Procedures and timeframes for collecting study products, returning study products, and completing all required documentation should be agreed upon by pharmacy and clinic staff and specified in relevant MTN-042 SOPs.

As with all product dispensing, the MTN-042 Record of Receipt of Participant-Specific Study Product (see Section Appendix 6-3) must be used to document dispensing of participant-specific study products to clinic staff who conduct off-site visits. The MTN-042 Off-Site Visit Log (available on the MTN-042 website under Study Implementation Materials) must be used to document transport and delivery/return of study products for off-site visits. One participant specific MTN-042 Off-Site Visit Log should be completed for each trip away from the study site to conduct off-site visits. This log will be returned to the pharmacy upon return to the study site, on the same day as the off-site visit. This log will remain in the participant's file in the pharmacy.

When completing the MTN-042 study Product Request Slip, clinic staff will indicate on the slip that the re-supply will be done in the context of an off-site visit. Upon receipt of a completed and signed MTN-042 Study Product Request Slip for an off-site visit, the PoR will prepare the participant-specific vaginal ring(s) or Truvada tablets (as a Resume request or in rare instances a Re-Supply request) and retain the product in the pharmacy until the date and time of pick-up for the off-site visit.

Any previously dispensed study product, including used/unused rings and unused tablets, should be collected during the off-site visit and returned to the clinic. Unused rings and tablets should be returned to the pharmacy for quarantine.

Pharmacy staff will complete the top section (CRS name and DAIDS CRS number) and the columns on the appropriate Record of Receipt. When receiving participant-specific study product from the pharmacy, clinic staff who conduct off-site visits will verify the PTIDs, confirm that only one ring or bottle is resumed for each PTID, and complete the remaining three columns on the Record of Receipt for each PTID. 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 pharmacy. When receiving participant-specific study product from the pharmacy, in addition to completing the Record of Receipt for each PTID, clinic staff who conduct off-site visits will complete the first six columns on the MTN-42 Off-Site Visit Log for each PTID. In addition, they will complete the top section (CRS name, DAIDS site ID number, date and PTID) on the MTN-042 Off-Site Visit Log.

Clinic staff are responsible for controlling access to study products dispensed into their custody and ensuring that the participant-specific study products are delivered to the participants for whom they were dispensed. Clinic staff also must retain and control access to their Off-site Visit Logs until the logs are returned to the pharmacy, at which time pharmacy staff assumes responsibility for the logs. Clinic staff who conduct off-site visits will transport participant-specific study product to the location of the off-site visit. During transport, study products should be stored securely (e.g., in a locked vehicle), with access limited to authorized clinic staff. Temperature should be controlled to the extent possible during transport. Site SOPs should outline steps that will be taken to document that the temperature during transport was maintained at 20 º- 25 º C with allowable excursion between 15º-30ºC. Temperatures experienced during transport must be documented on the Off-site Visit Log. The site pharmacist and MTN pharmacist should be notified if a temperature excursion is reported. If the dispensed study product leaves the clinic but is not delivered to the participant off-site (i.e., participant could not be located) the clinic staff will document this appropriately in the pharmacy accountability log and off-site log and return the study product to the pharmacy for quarantine.

Clinic staff will complete the six columns on the left portion of the Off-site Visit Log. In the course of conducting each off-site visit, clinic staff will document the number of vaginal rings or bottles of tablets delivered to participants on the MTN-042 Off-site Visit Log. For the study product NOT being delivered (i.e., the ring or the tablet) the columns on the form should be marked “N/A”. Delivery of the study product must be documented on the Participant-Specific Dispensing Record and the accountability log in the pharmacy, and may also be documented in chart notes, on visit checklists, or on other source documents designated, per site SOP, for this purpose by clinic staff. Clinic staff will return the completed log to the pharmacy. If completed logs are not returned to the pharmacy, pharmacy staff will not dispense any participant-specific study product for off-site visits on the following day (until the previous day’s logs are received). Pharmacy staff will retain the completed log in the pharmacy. Comments may be recorded in the designated column and, if additional space is needed, on the back of the log.

6.5.4 Clinic Study Product Destruction Log

The Clinic Study Product Destruction Log (available on the MTN-042 website under Study Implementation Materials) should be completed to document the destruction of the used ring in the specific biohazard waste container/bin. This will be the final documentation required for documenting the accountability of any used ring that is not destined for further testing. If a ring is inserted in the clinic and then removed, during the same visit, due to an adverse event or error subsequently discovered, the ring would be placed in the container for destruction. When the container is sent for destruction a copy of the destruction must be sent to the site pharmacist and retained in the pharmacy study file.

6.6 Specimen Storage CRF

Site staff must document collection and storage of all returned used VRs *that are intended for testing* on the Specimen Storage CRF, as well as the Participant-Specific Clinic Study Product Accountability Log.

After documenting the return of used rings on the Specimen Storage CRF (if intended for testing) and clinic log, clinic staff should proceed to follow the directions outlined in SSP section 10 (Laboratory Considerations). The placement of the used ring in the biohazard bag that is to be stored is documented on the Participant-Specific Clinic Study Product Accountability Log.

In the unusual event that a VR was dispensed but never inserted, the unused VR must be returned to the clinic and the event documented by study staff on the Participant-Specific Clinic Study Product Accountability Log. The unused VR should be returned to the pharmacy for quarantine. Only unused VRs (never inserted into the vagina) and Truvada tablets may be returned to the pharmacy. Clinic staff and pharmacy staff will complete the Pharmacy Record of Return of Site-Specific Unused VRs or Unused Truvada Tablets (Appendices 6-4a and 6-4b).

6.7 Study Product Return and Retrieval

Protocol Section 6.5 specifies the circumstances under which study product must be retrieved from participants. Study participants will be instructed to bring all study products (unused tablets and unused/used VRs) to the site at each 4-week visit (cohorts 2-4) or at the 2nd bi-weekly visit (cohort 1). Clinic staff should collect the unused study products and return them to the site pharmacy.

Participants will be instructed to return all study products (unused tablets and used/unused VRs) at their PPO visit. If the participant does not bring her study product(s) to this visit study staff must arrange to retrieve the VR(s) or tablet(s) with ten (10) business days of her pregnancy outcome. Site staff will make every effort to encourage participants to return study products as soon as possible. If study product is left at the hospital or delivery facility, every effort should be made to retrieve the study product and all efforts to do so should be documented.

Refer to Table 6-2 below for reasons for study product retrieval and timeframe of retrieval. If study product is not returned to the site within the time frames outlined, then the MTN-042 PSRT must be notified.

Table 6-2: Product Retrieval Timeframes

Condition	Timeframe for Retrieval
Permanent discontinuation due to potential HIV infection or Grade 3 or higher renal or hepatic toxicity	Within 24 hours
Permanent discontinuation for any other reason or IoR discretion	Within 5 working days
Temporary hold for reasons with expected duration of at least 7 days	Within 7 working days
Pregnancy outcome (e.g., delivery)	Within 10 working days

The retrieved study product must be documented by clinic staff on the Specimen Storage CRF (rings only) and both the rings and tablets on the Participant-Specific Clinic Study Product Accountability Log (available on the MTN-042 website under Study Implementation Materials). If the study product cannot be retrieved (i.e., participant disposed of it or it was lost), this must be documented on the Protocol Deviation Log CRF and the Participant-Specific Clinic Study Product Accountability Log. Related details and counseling around the need to ensure return of study product to site should be detailed in the participant's chart notes.

6.8 Study Product Complaints

During the study, a problem or concern may be observed with either study product. A problem may be noted by the pharmacy staff, clinic staff, or the participant. These complaints may be about the

dosage form (VR or oral tablets), packaging (overwrap pouch, bottle), or other aspects of the study product. Clinic staff should make thorough record of complaints of participants and clinic staff. The clinic staff member will notify (via email) the site PoR and other designated site pharmacy staff of the study product complaint. This notification should include as much detail as possible. The following information should be provided in the email: PTID, date of the observed issue, date that the issue was reported, date study product was dispensed, whether an adverse event occurred, description of the nature of the issue, pictures (if relevant), and any other details deemed necessary.

The site PoR will forward (via email) this information to the MTN LOC Pharmacist. The MTN LOC Pharmacist will forward the study product complaint to IPM or Gilead. If the complaint/issue is concerning an unused study product, then the unused product should be quarantined in the pharmacy. If the complaint/issue is concerning a used VR, then the clinic staff should process/store the VR per SSP Section 10 (Laboratory Considerations).

Appendix 6-1: MTN-042 Prescription

MTN-042 PRESCRIPTION

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

CRS Name:		CRS ID:		CRS Location:	

Participant ID: ☐☐☐ – ☐☐☐☐☐☐ **Visit #**_____

Did the participant provide written informed consent for enrollment into MTN-042?	Yes ☐	No ☐	Clinic Staff Initials: _____

Indicate Cohort:

☐ Cohort 1 ☐ Cohort 2 ☐ Cohort 3 ☐ Cohort 4

Indicate Study Product:

☐ **Dapivirine Vaginal Ring**	☐ **Truvada Tablets**
Sig: Insert one (1) ring into the vagina as directed. **Quantity:** One vaginal ring. May be refilled as needed per request by designated clinic staff on MTN-042 Study Product Request Slip for duration of indicated study product use period.	**Sig:** Take one (1) tablet by mouth once daily as directed. **Quantity:** One bottle of Truvada tablets (30 tablets/bottle). May be refilled as needed per request by designated clinic staff on MTN-042 Study Product Request Slip for duration of indicated study product use period.

Authorized Prescriber Name *(please print)*: _____

Authorized Prescriber Signature: _____

Date: ☐☐ – ☐☐☐ – ☐☐
dd *MMM* *yy*

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Pharmacy

Appendix 6-2: MTN-042 Study Product Request Slip

MTN-042 STUDY PRODUCT REQUEST SLIP

Instructions: Complete the CRS name, ID # and location. Complete the PTID and check the cohort. Indicate the visit #. Mark whether this is a study product re-supply (if so, indicate which study product and quantity), clinical hold, resume (after a clinical hold), participant decline, clinical permanent discontinuation, or product use completion notification. Only an authorized prescriber can indicate product resumption. Deliver the original white copy (labeled "Pharmacy") to the pharmacy. File the yellow copy (labeled "Clinic") in the participant's study notebook.

CRS Name:		CRS ID:		CRS Location:	

Participant ID: ☐☐☐ – ☐☐☐☐☐☐ **Visit #:** _____

Indicate Cohort:

☐ Cohort 1 ☐ Cohort 2 ☐ Cohort 3 ☐ Cohort 4

☐ **RE-SUPPLY** → **Pharmacy: (Check one)**
- ☐ Dispense _____ dapivirine vaginal ring(s)*
- ☐ Dispense _____ bottle(s) of Truvada tablets (30 tablets/bottle)*

***Reason >1 VR or bottle:** _____

☐ **HOLD** → **Pharmacy:** **Do not** dispense study product to the participant until another MTN-042 Study Product Request Slip marked "RESUME" is received.

Reason: _____

☐ **RESUME** → **Pharmacy: (Check one)**
- ☐ Dispense one (1) dapivirine vaginal ring
- ☐ Dispense one (1) bottle of Truvada (30 tablets/bottle)

Only an authorized prescriber can indicate RESUME.

☐ **PARTICIPANT DECLINE** → **Pharmacy:** **Do not** dispense at this visit – participant is refusing study product.

☐ **PERMANENT DISCONTINUATION** → **Pharmacy:** **Do not** dispense any further study product to the participant.

Reason: _____

☐ **PRODUCT USE COMPLETED** → **Pharmacy:** **Do not** dispense any further study product to the participant.

Clinic Staff Name *(please print)*: _____

Clinic Staff Signature: _____

Date: ☐☐ – ☐☐☐ – ☐☐
dd *MMM* *yy*

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Pharmacy

Appendix 6-3: MTN-042 Record of Receipt of Study Product

MTN-042 RECORD RECEIPT OF STUDY PRODUCT (DAPIVIRINE VR and Truvada Tablets)

PHARMACY STAFF					CLINIC STAFF/ RUNNER		
PTID	Date/Time dispensed from pharmacy dd-mm-yy (hh:mm) 24 hr clock	**Indicate dapivirine VR or Truvada Tablets**	Number of VRs or Bottles Dispensed by Pharmacy	RPh Initials	Date and Time Received from Pharmacy dd-mm-yy (hh:mm) 24 hr clock	Clinic Staff/ Runner Initials	Comments

Instructions: Complete one row each time a VR or bottle of tablets is dispensed to non-pharmacy staff for delivery to a study participant. All entries must be in dark ink. Corrections may be done by drawing a single line through incorrect entries, entering correct information, and initialing and dating the correction.

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Appendix 6-4a: MTN-042 Record of Return of Site-Specific Unused Dapivirine VRs

MTN-042 RECORD OF RETURN OF UNUSED DAPIVIRINE VAGINAL RINGS

CRS Name:	CRS ID:

CLINIC STAFF				PHARMACY STAFF				
Date Returned to Pharmacy (dd-MMM-yy)	PTID	**No. of VRs**	Clinic Staff/ Runner Initials	Date Received by Pharmacy (dd-MMM-yy)	PTID (verify)	Reason for Return	RPh Initials	QA against Destruction Form Pharmacy Staff Initials

Instructions: Complete one row each time an unused VR 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.

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MTN-042 RECORD OF RETURN OF SITE-SPECIFIC UNUSED TRUVADA TABLETS

CRS Name:	CRS ID:

CLINIC STAFF				PHARMACY STAFF				
Date Returned to Pharmacy (dd-MMM-yy)	PTID	No. of Tablets	Clinic Staff/ Runner Initials	Date Received by Pharmacy (dd-MMM-yy)	PTID (verify)	Reason for Return	RPh Initials	QA against Destruction Form Pharmacy Staff Initials

Instructions: Complete one row each time unused tablet(s) are 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.