[Site Name]

Standard Operating Procedure (SOP)

SOP No.: MTN-042/MTN-043, template version 1.1

Title: MTN-042/MTN-043 Clinic Study Product Accountability and Destruction (non-pharmacy)

Original Effective Date: XX MMM YYYY Revision Effective Date: Not Applicable

PURPOSE

The purpose of this Standard Operating Procedure (SOP) is to provide guidance for oversight and accountability of study product dispensed and returned during the MTN-042 and MTN-042 trials in accordance with US Food and Drug Administration (FDA) and International Conference on Harmonization Good Clinical Practice (ICH/GCP) Standards.

SCOPE

The policy applies to study product provided to participants and collected from participants during the MTN-042 and MTN-043 trials. This includes used rings for transfer to the laboratory for storage, for disposal/destruction, and unused rings and tablets for transfer to the pharmacy for quarantine and documentation of all of the above.

INTRODUCTION

Traditionally, study product is dispensed and returned to the site pharmacy in a process that is separate and independent of study activities performed in the site clinic. Because of the unique design of these trials, accommodation must be made to allow for distribution, removal and collection of study product (both unused rings and tablets, and used rings) at the site clinic.

To achieve the goals of the protocol and maintain compliance with regulatory requirements, a standardized process of tracking and accountability will be adopted and followed by all MTN-042/MTN-043 sites. The tracking and accountability process is designed to preserve and document the chain of custody of the vaginal ring and tablets at the site clinic. This includes tracking the date the ring or bottle of tablets is distributed to the study participant, the date the ring or unused tablets are returned to the clinic, and the date of either shipment to an outside laboratory for further testing or destruction (used ring only). The tablets are sent to the pharmacy for quarantine and subsequent destruction. The requirements of this process are described in this SOP.

The provision, collection and/or destruction of study product (used and unused) are recorded on the Participant-Specific Clinic Study Product Accountability Log (Appendix II) and/or the Clinic Study Product Destruction Log (Appendix III). These logs, in addition to any documentation pertaining to the destruction of the containers contents (third party destruction certificates or other documentation and/or communications) must be retained as part of the site’s Regulatory Files.

DEFINITIONS

Study product: Any drug, biologic, vaccine, radiopharmaceutical, item or device that is either provided for the study or identified in the protocol as being a study product. Study product hereinafter is referred to as “Dapivirine 25mg vaginal ring and oral Truvada tablets”

Quarantined (unused) vaginal rings: All vaginal rings that have been assigned per protocol to a study participant, but never used according to the intended investigational purpose (i.e., inserted into the vagina) and are collected from the participant and transferred to the pharmacy for quarantine (per the pharmacy SOP). This includes those whereby the package has been opened, but the ring never inserted.

Quarantined (unused) tablets: All tablets that are returned by the participant are collected from the participant and transferred to the pharmacy for quarantine (per the pharmacy SOP).

Participant-Specific Clinic Study Product Accountability Log: This log is required documentation for study product tracking per participant and is part of the Drug Accountability Records that help ensure that all study product is accounted for in the clinical trial. This log is available on the MTN-042 and MTN-043 Study Implementation Materials webpage.

Clinic Study Product Destruction Log: This log is required documentation for tracking rings that that are not stored and require destruction.

Used vaginal rings for destruction: All used vaginal rings that are inserted in the clinic but subsequently removed that same day prior to the participant leaving the clinic for any reason and sent for destruction. These rings must be placed in a designated container/bin and disposed of in accordance with the CFR and ICH guidelines for Good Clinical Practice and in accordance with guidelines established by [s*ite to reference any local regulatory guidelines here, if different from what is outlined in this template*.] They are considered biohazardous waste and must be placed in a suitable container/bin and subsequently destroyed.

Used vaginal rings for storage: All vaginal rings that have been used in the way they were intended (i.e., inserted into the vagina). These rings will be stored and transferred to the study specific laboratory for future testing.

RESPONSIBILITIES

The clinic responsibilities of accountability and tracking of the vaginal ring and tablets will begin at the time the study product is dispensed to clinic staff by the site pharmacy (see MTN-042 or MTN-43 Pharmacy Chain of Custody SOPs) and will end when the clinic ships used study product (used rings) to the study-specified laboratory for testing, and/or when study product (used rings) are sent outside of the clinic for destruction, and/or when unused product (ring or tablets) are returned by the participant and provided back to the pharmacy for quarantine.

MTN-042 and MTN-043 IoRs have ultimate responsibility for ensuring that the team members involved in collecting study product from participants are knowledgeable and follow the guidelines outlined in this SOP.

MTN-042 and MTN-043 staff members delegated by the IoR who deliver/provide and collect study product from participants are responsible for understanding and following this SOP.

MTN-042 and MTN-043 Study Coordinators or other designee is responsible for training study staff on the procedures and processes of documenting product delivery and collection, in accordance with this SOP, and for day-to-day oversight of such.

It is the responsibility of the [*site to insert individual responsible*] at the site to perform a QA/QC on this process and ensure that the Participant-Specific Clinic Study Product Accountability Log is accurately completed and consistent with other source documentation.

[*Site to insert individual responsible*] will be responsible for completing and maintaining the Participant-Specific Clinic Study Product Accountability Log and the Clinic Study Product Destruction Log.

PROCEDURES

1. Documentation of ring and tablet provision
   1. Site clinic staff will provide vaginal rings or tablets to study participants directly in the clinic. [*Site to outline procedures and responsibilities from the time the study product leaves the pharmacy, until it is delivered to the participant. Procedures for verifying participant identity prior to product provision should be included.*]
2. Collecting used rings for transfer to the laboratory
   1. All used vaginal rings, including rings previously removed by the participant outside of the clinic and rings removed during the clinic visit are expected to be collected for transfer to the laboratory.
   2. All collection procedures will be conducted in the clinic and will follow guidance per current SSP Section 6.
   3. [*Site to specify any/which processing procedures that will be conducted in the clinic vs. the lab as outlined in the SSP*.]
3. Collecting unused rings or tablets for transfer to the pharmacy
   1. Unused vaginal rings or tablets must be returned to the pharmacy for quarantine and subsequent destruction, the same day it is determined that the dispensed ring will not be inserted or the same day the unused ring or tablets are returned to the clinic.
4. Collecting used rings for destruction
   1. Although used vaginal rings are expected to be collected for transfer to the laboratory, there may be the need to send a ring for destruction. In the event that a ring is inserted in the clinic but subsequently removed that same day prior to the participant leaving the clinic for any reason (i.e. it is determined that a product hold is warranted but not identified prior to ring dispensation and insertion) the ring should be sent for destruction.
   2. The ring may be placed in [*site to insert a container deemed suitable to place the used VR, such as the amber return bag provided by the pharmacy which is given to participants*] and this will then be placed in the designated biohazard waste container/bin in the [*site to insert location of biohazard waste container/bin e.g. exam room, study coordinator office*]. *[Site to reference any additional local regulatory guidelines here, if different from what is outlined in this template.]*
   3. [*Site to insert method of identifying the biohazard containers/bins so that destruction of a specific ring can be identified e.g..* a *sharps container/box lined with the red bag and a labeled with the words “Medical Waste” or “Bio-Hazardous” or “Infectious” and/or contain the universal Biological Hazard Symbol affixed to the container*]. Vaginal rings marked for destruction will be destroyed [*site to insert timeframe e.g. periodically throughout the study or at the end of the study*].
   4. The contracted company responsible for the collection, transport or disposal of waste is [*Site to insert the contracted waste disposal representative/company name*].
   5. The destruction of the biohazard container must be documented by the party responsible for the destruction. Proper records shall be maintained concerning storage, transportation and final disposal of medical waste generated. These records will be maintained and available for review upon request. [*Site to include the name/type of report provided by the contracted waste disposal representative/company name, the site staff responsible for receiving this report, and site staff responsible for ensuring the report is filed e.g. written certification/note to file signed by the contracted waste disposal representative to the effect that waste has been properly treated and destroyed.*]
5. QA/QC Procedures
   1. *[Site to outline the QA/QC procedures- when this will be conducted, how frequently and by whom.*]

Appendices

Appendix I: Participant-Specific Clinic Study Product Accountability Log Completion Instructions

Appendix II: Participant-Specific Clinic Study Product Accountability Log

Appendix III: Clinic Study Product Destruction Log

References

MTN-042 SSP Manual Section 6

MTN-043 SSP Manual Section 6

History

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| Version Number | Date | Supersedes | Review Date | Change |
| 1.0 | XX | NA | NA | Initial Release |
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Approval

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|  | Reviewer, Reviewer’s Title |  |  | Date |

**APPENDIX I:** Participant-Specific Clinic Study Product Accountability Log: Maintenance and Completion Instructions

1. Maintenance of the Log
2. Blank copies of the log should be maintained centrally at the clinic site and photocopies may be made when additional blank log pages are needed
3. Each participant file should have a Participant-Specific Clinic Study Product Accountability Log. Site staff at the clinic should complete the PTID found in the header of each page of the log
4. The log should be treated as confidential
5. Completion of the Log When a Ring or Tablets are Provided in the Clinic
6. At each visit when study product is provided to a study participant, the site staff should complete one row found under the *PROVIDED* heading of the log.
7. Record information pertaining to the provision of the study product to the participant including the *Date Provided to Participant*, and *Visit Code*.
8. Site staff completing the log should also record their initials and date in the *Clinic Staff Initials* and *Date* column.
9. If pertinent, site staff should record any additional relevant comments about the provision of the study product in the *Comments* column of the log.
10. Completion of the Log When a Ring or Tablets are Returned to the Clinic
11. At each visit when a ring or unused tablets are returned to the clinic from a study participant, the site staff should complete the row found under the *RETURNED* heading of the log *that corresponds to the visit when the ring or tablets were provided to the study participant.* In most circumstances, this will correspond to the column on the log that contains the date of the participant’s last visit.
12. Record the information pertaining to the return of the ring or unused tablets including the *Date Returned*, *Visit Code*, *Quantity of product returned (for example, 1 vaginal ring, or 4 tablets), Used Rings Stored for Lab (record date to lab)*, *Used Rings Returned for destruction (record bin # and place in Destruction Container)* and *Destruction Container Code, and Unused Ring or Tablets Returned and Sent to Pharmacy* (unused study product that will be quarantined in the Pharmacy)*.If the participant does not return study product, this should also be indicated on the log.*
13. Site staff completing the log should also record their initials and date in the *Clinic Staff Initials* and *date* columns.
14. Completion of the Clinic Study Product Destruction Log When a Destruction Container is Destroyed
15. When a Destruction Container is removed from the clinic for destruction of its contents (used vaginal rings), site staff should complete one row on the Clinic Study Product Destruction Log. This will be the final documentation required for documenting the accountability of the used ring that is not destined for further testing in the laboratory
16. Record information pertaining to the destruction of the container including the *Destruction Container Code* and *Date Sent for Destruction or* *Date of Destruction*.
17. If pertinent, site staff should record any additional relevant comments about the destruction of the container in the *Comments* column of the log.
18. Site staff completing the log should also record their initials in the *Staff Initials* column.