[Site Name]

Standard Operating Procedure (SOP)

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Title: Clinic Study Product Accountability and Destruction (non-pharmacy) for MTN-024/IPM 031

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-024/IPM 031 trial 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-024/IPM 031 trial. This includes used rings for transfer to the laboratory for storage, for disposal/destruction, and unused rings 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 this trial, accommodation must be made to allow for distribution, removal and collection of study product (both unused and used) 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-024/IPM 031 sites. The tracking and accountability process is designed to preserve and document the chain of custody of the vaginal ring at the site clinic. This includes tracking the date the ring is distributed to the study participant, the date the ring is returned to the clinic, and the date of either shipment to an outside laboratory for further testing or 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 and/or the Clinic Study Product Destruction Log. 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 “vaginal ring(s)”

Quarantined (unused) vaginal rings: All vaginal rings that has 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.

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-024/IPM 031 Study Implementation Materials webpage.

Clinic Study Product Destruction Log: This log is required documentation for tracking study product that is not stored and requires destruction. This log is available on the MTN-024/IPM 031 Study Implementation Materials webpage.

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 (i.e., the wrong ring has been given or it is determined that a product hold is warranted but not identified prior to ring dispensation and insertion) 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) and are collected at the 4-Week, 8-Week and 12-Week visits. 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 will begin at the time the vaginal ring is dispensed to clinic staff by the site pharmacy (see MTN-024/IPM 031 Pharmacy Chain of Custody SOP) 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 is returned by the participant and provided back to the pharmacy for quarantine.

MTN-024/IPM 031 Investigator of Record (IoR) has ultimate responsibility for ensuring that the team members involved in collecting vaginal rings from participants are knowledgeable and follow the guidelines outlined in this SOP.

MTN-024/IPM 031 staff members delegated by the Investigator of Record who deliver/provide vaginal rings to and collect vaginal rings from participants are responsible for understanding and following this SOP.

MTN-024/IPM 031 Study Coordinator or other designee is responsible for training study staff on the procedures and processes of documenting ring 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 provision and collection
   1. Site clinic staff will provide vaginal rings 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 ring 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 10.
   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 for transfer to the pharmacy
   1. Unused vaginal ring must be returned to the pharmacy for quarantine the same day it is determined that the dispensed ring will not be inserted or the same day the ring is 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. the wrong ring has been given or 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 II: Clinic Study Product Destruction Log

References

MTN-024/IPM 031 SSP Manual Section 6

History

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| --- | --- | --- | --- | --- |
| Version Number | Date | Supersedes | Review Date | Change |
| 1.0 | 08 August 2013 | NA | NA | Initial Release |
| 1.1 | 30 September 2013 | Version 1.0 | 30 September 2013 | Clarify destruction procedures and definition of used rings sent for destruction. |

Approval

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

APPENDIX 1: 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 is Provided in the Clinic
6. At each visit when a ring 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 ring to the participant including the *Date Ring 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 ring in the *Comments* column of the log.
10. Completion of the Log When a Ring is Returned to the Clinic
11. At each visit when a ring is 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 was 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 including the *Date Ring Returned*, *Visit Code*, *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 Returned and Sent to Pharmacy* (unused ring that will be quarantined in the Pharmacy), *.If the participant does not return a ring, 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.

APPENDIX II

MTN-024/IPM 031 Participant-Specific Clinic Study Product Accountability Log

Participant ID:

Instructions: Complete one row for each ring provided to the participant. Record the Date Provided, Visit Code, Staff Initials and Date. When the participant comes to her next visit and the ring is returned (or expected to be returned), complete the Date Returned, Visit Code, the appropriate Ring Status, Staff Initials and Date. This information should also be recorded in the event of an off-site visit if the ring is collected. Recording the Ring Status: If a ring is returned and set aside for storage, check the box for that option and record the date the ring was sent to the lab. If a ring is returned and set aside for destruction, check the box for that option and record the destruction bin #. If an unused ring was returned, check the box for that option and return the ring to the pharmacy on the same day. If a ring is not returned as expected, check the box for that option. Record Staff Initials and Date. Update if the ring is returned. 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. Comments may be entered at any time.

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|  | PROVIDED | | | | | RETURNED | | | | |
| Ring | Date Provided (dd-MMM-yy) | Visit Code (##.#) | Staff Initials | Date | Comments | Date Returned (dd-MMM-yy) | Visit Code (##.#) | Ring Status | Staff Initials | Date |
| 1 |  |  |  |  |  |  |  | * Used ring for storage: date to lab\_\_\_\_\_\_\_\_\_\_ * Used ring for destruction: bin # \_\_\_\_\_\_\_\_\_\_ * Unused ring to pharmacy * Ring not returned |  |  |
| 1 |  |  |  |  |  |  |  | * Used ring for storage: date to lab\_\_\_\_\_\_\_\_\_\_ * Used ring for destruction: bin # \_\_\_\_\_\_\_\_\_\_ * Unused ring to pharmacy * Ring not returned |  |  |
| 1 |  |  |  |  |  |  |  | * Used ring for storage: date to lab\_\_\_\_\_\_\_\_\_\_ * Used ring for destruction: bin # \_\_\_\_\_\_\_\_\_\_ * Unused ring to pharmacy * Ring not returned |  |  |

APPENDIX II: Clinic Study Product Destruction Log

Clinic Study Product Destruction Log

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| Name of Site: |  | DAIDS Site Number: |  |
| Protocol Title: | MTN-024/IPM 031: Phase 2a Safety Study of a Vaginal Matrix Ring Containing Dapivirine in a Postmenopausal Female Population | | |
| Site Investigator: |  | Phone Number: |  |

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| Destruction Container Code/Bin # | Date Sent for Destruction | Clinic Staff Initials | Date of Destruction | Clinic Staff Initials | Comments |
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