

Section 3. Documentation Requirements

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Study staff members are responsible for proper collection, management, storage, quality control, and quality assurance of all study-related documentation. This section contains information on the essential documents that each study site must maintain throughout the study. It also contains information related to establishing adequate and accurate participant research records for MTN-025.

3.1 Essential Documents

The DAIDS policy on *Requirements for Essential Documents at Clinical Research Sites Conducting DAIDS Funded and/or Sponsored Clinical Trials* and *E6 Good Clinical Practice: Consolidated Guidance* specifies the essential documents that study sites must maintain. Although all required documentation must be available for inspection at any time, all documents need not be stored together in one location. A suggested essential documents filing structure is available upon request from FHI 360. Study sites are not required to adopt the suggested structure but are encouraged to consider it when developing their filing approach for the study. Further clarifications of the suggested filing structure are as follows:

- Essential documents may be stored in files and/or in binders. The files/binders listed in essential documents filing structure may be further subdivided, consolidated, and/or re-organized.
- It is recommended that a contents sheet be maintained and inserted as the first page(s) of each file/binder. Within each file/binder, it is recommended that documents be filed in ascending date order (most recent documents in front).
- Certain documents related to the investigational study products will be stored in site pharmacies. A listing of essential documents to be maintained in the pharmacies is provided in Section 3.3.

- To facilitate routine inspection by study monitors, certain laboratory-related essential documents should be stored in the main study essential documents files/binders. Other lab-related essential documents (e.g., lab SOPs) may be filed in site laboratories.
- The suggested filing structure assumes that MTN-025 participant research records will be stored separately from the other essential documents. Section 3.2 below provides information on the required contents of these records.
- The MTN-025 Screening and Enrollment Logs and PTID-Name Linkage Log must be maintained in hard-copy unless an electronic system is 21 CFR Part 11 compliant. The suggested filing assumes that these logs will be stored in the study clinic or data management area throughout the screening and accrual process and not necessarily with the other essential documents listed.
- All significant communications between the study sponsor and/or management team and study sites should be printed and filed with other essential documents. Examples of significant communications include, but are not limited to:
 - All site responses to priority emails (thereby indicating they were read and responded to)
 - All study management team and/or sponsor communications that document agreements or significant decisions involving trial administration or conduct, protocol deviations, eligibility and informed consent, safety and/or study endpoints, or study product
 - All notifications of critical events (CE) that are submitted to the Division of AIDS
 - Protocol Team call slides
 - Final reports from assessment visits conducted by FHI 360, Network Lab, or others on the study management team as well as the completed list of action items stemming from the report
 - Emails from the study management team that specify to print and file

Note: When required documents are modified or updated, the original and all modified or updated versions must be retained. Communications that are PTID-specific should be printed and filed in the participant binder. Communications that are overarching (i.e. are not PTID-specific) can be printed and filed in regulatory documentation. All clinical site monitoring reports and correspondence can be accessed through the DAIDS-ES system and do not need to be printed and filed.

3.2 Financial Disclosure Forms

Each clinical investigator listed on the Form 1572 must disclose any financial interests that may be affected by the outcome of the research or attest to the absence of relevant significant financial interests. Per 21 CFR 312.53, financial disclosure must be completed prior to study involvement. The IoR and site Regulatory Coordinator must ensure that *prior to* completing (adding or removing investigators) and signing the FDA Form 1572, all investigators listed on the form must complete and sign the study-specific financial disclosure form (FDF). In addition, investigators listed on the current FDA Form 1572 must submit a new FDF at the completion of all study-specific activities (i.e. the date of the last participant follow-up visit at the study site).

A blank FDF is available on the MTN-025 webpage. All items can be entered electronically except for the signature and date. The ‘*Study start date*’ is date on the cover of the most current version of the protocol. The ‘*Study end date*’ is the date of last follow-up at the site; this section on the FDF form may be left blank until the end of follow-up at the site.

At the beginning of the study and throughout study duration, whenever an FDF is completed, sites should upload the form to the DAIDS Protocol Registration System (DPRS), under the “Other” submission category. Training slides on the requirements for FDF completion can be found here: <http://www.mtnstopshiv.org/node/1639>.

3.3 Participant Research Records

Study sites must maintain adequate and accurate participant research records containing all information pertinent to MTN-025 for each study participant. See protocol section 13.6 for further information regarding all participant information which should be stored in locked file cabinets with access limited to authorized study staff.

The International Conference on Harmonization (ICH) Consolidated Guidance for Good Clinical Practice (GCP) defines the terms source data and source documentation as follows:

The term **source data** refers to all information in original records and certified copies of original records related to clinical findings, observations, or other activities in a clinical study necessary for the reconstruction and evaluation of the trial (including all screening, enrollment and randomization activities). Source data are contained in source documents (e.g., original records or certified copies).

The term **source document** refers to original documents, data, and records (e.g., hospital records; clinical and office charts; laboratory records and notes; memoranda; participants’ diaries and/or evaluation checklists; pharmacy dispensing records; recorded data from automated instruments; copies of transcriptions certified after verification for accuracy and completeness; microfiche; photographic negatives; microfilm or magnetic media; x-rays; participant files; and records kept at the pharmacy, laboratories, and medico-technical departments involved in the study).

Source documents are commonly referred to as the documents—paper-based or electronic—upon which source data are first recorded. All study sites must comply with the standards of source documentation specified in the DAIDS policy on *Requirements for Source Documentation in DAIDS Funded and/or Sponsored Clinical Trials*. The DAIDS policy specifies both requirements and recommendations. Study sites must comply with all requirements and are encouraged, but not required, to comply with all recommendations. The DAIDS Source Doc SOP can be accessed on the MTN website: <http://www.mtnstopshiv.org/node/4537>.

3.4 Required Source Documentation

For MTN-025, participant research records should consist of the following source documents:

- Chart notes
- Documentation that the participant provided written informed consent to screen for and participate in the study prior to the conduct of any study procedures
- Documentation that the participant met the study's eligibility criteria
- A record of the participant’s use of the investigational study products

- Pharmacy investigational product dispensing and chain of custody records (maintained in the study site pharmacy), as well as clinic study product accountability documentation (maintained in the study clinic)
- A record of all contacts, and attempted contacts, with the participant
- A record of all procedures performed by study staff during the study (e.g. on visit checklists and/or other site-specific procedural flow sheets or chart notes)
- Local laboratory testing logs and result reports, or other as defined as a source document for a test result.
- Case report forms (CRFs) and other forms provided by the MTN Statistical and Data Management Center (SDMC) or MTN LOC
- Study-related information on the participant’s condition before, during, and after the study, including:
 - Data obtained directly from the participant (e.g., interview and/or other self-reported information)
 - Data obtained by study staff (e.g., exam and lab findings)
 - Data obtained from non-study sources (e.g., non-study medical records)
- Other source documents (e.g., site-specific worksheets)

As a condition for study activation, each study site must establish an SOP for Source Documentation that specifies the source documents for all study procedures. To establish consistency in source documentation across sites the source for specific study procedures will be provided within the Source Documentation SOP template (available on the MTN-025 website: <http://www.mtnstopshiv.org/node/7330>). Supplemental information on the use of chart notes, visit checklists, and forms provided by the MTN SDMC or MTN LOC is provided below. Detailed information on proper completion, maintenance, and storage of participant product dispensing documentation is provided in Section 9 of this manual, and the MTN-025 Pharmacist Study Product Management Procedures Manual. Detailed information on proper completion of CRFs is provided in the CRF Completion Guidelines provided by the MTN SDMC.

3.4.1 Chart Notes

Study staff must document every contact with a study participant in a signed and dated chart note or contact log specifying the following information:

- Visit date at which a contact takes place or at which a particular procedure takes place
- Visit type (scheduled, interim, etc.)
- Purpose of the visit and location of the contact if other than the research clinic
- General status of the participant at the time of the visit

Chart notes also should be used to document the following:

- The informed consent processes (if an Informed Consent Coversheet is not used)
- Procedures performed that are not recorded on other source documents
- Additional information related to clinical exam findings to ensure appropriate follow-up
- Study-specific counseling sessions and any associated referrals that are not documented on other source documents
- Other pertinent data about the participant that are not recorded on other source documents
- Reason(s) why protocol-specified procedures were not performed
- Contact attempts to follow up on participants who missed a scheduled study visit

Chart notes should be written in the order that the participant contacts occurred, but documentation of the specific times procedures occurred is not necessary unless specified in the study protocol or this manual. In the event a staff member neglects to document a participant contact in real time, an addendum to clarify that this occurred should be included in the chart note (addendums should also be signed and dated using the date they were written).

3.4.2 Visit Checklists

Checklists are convenient tools which may serve as source documentation if designed and completed appropriately. These checklists alone may not be sufficient for documenting all procedures, but can be used to indicate that the procedure was completed. Chart notes may be required to supplement this for any of the reasons mentioned above. Visit Checklist templates are available on the MTN-025 website (<http://www.mtnstopshiv.org/node/7330>).

Instructions for completing visit checklists in accordance with source documentation requirements are outlined below. Note that these instructions are based off the layout of the template visit checklists and may vary slightly depending upon how a site chooses to modify the templates. The IoR is ultimately responsible for ensuring that source documentation requirements are met:

- Enter the participant identification number (PTID) and visit date in the top section of each checklist. If checklists are multiple pages, enter the PTID and visit date on each page.
- For screening visits, write the screening attempt number in the applicable checklist item.
- For follow-up visits, enter the visit month in the top section of each checklist.
- The “Required at visits” column indicates when the item is required during follow-up per-protocol. Complete staff initials next to procedures completed.
- Enter your initials only beside the procedures that you perform. Do not enter your initials beside procedures performed by other staff members. If other staff members are not available to initial checklist items themselves, enter, initial, and date a note on the checklist documenting who completed the procedure, e.g., “done by {name}” or “done by nurse.”
- If all procedures listed on a checklist are performed on the date entered in the top section of the form, the date need not be entered beside each item. If procedures listed on a checklist are performed on multiple dates, enter the date upon which each procedure is performed beside each item.
- For items on the checklist that contain checkboxes, one set of initials is still sufficient, even if multiple boxes are checked. Bracketing procedures which are consecutive and all done on the same date by the same staff is also acceptable.
- Entering multiple sets of initials for one procedure should be avoided as much as possible. If this is happening on a regular basis, the site should consider splitting the task into multiple items on the checklist so each procedure receives only one set of initials.
- If a procedure listed on the checklist is not performed, enter “N/D” for “not done” beside the item and record the reason why on the checklist (if not self-explanatory); initial and date this entry.

The sequence of procedures presented on the template visit checklists is a suggested ordering. In consultation with the MTN LOC (FHI 360), site staff should modify the checklists to maximize the efficiency of site-specific study operations. For example, sites should consider which cadre of staff are responsible for each procedure, and group procedures together as possible to minimize movement of the participant during the visit. Sites may alter the sequence of procedures, with the following exceptions:

- Informed consent for screening must be obtained before any screening procedures are performed. Screening procedures are listed in protocol Sections 7.2.
- Informed consent for enrollment must be obtained before any study enrollment or follow-up procedures are performed. Enrollment procedures are listed in protocol Section 7.3. Follow-up procedures are listed in protocol Section 7.4.
- Informed consent for screening and enrollment in the decliner group is required before any decliner group procedures are performed. See protocol section 7.5.1.
- On the day of enrollment, study product provision (if applicable, based on participant choice) must take place after final confirmation and verification of eligibility, administration of the Baseline Behavior Assessment, Baseline Vaginal Practices, Baseline Audio Computer Assisted Self-Interview (ACASI) Questionnaire, collection of blood for plasma archive, and self-collected vaginal swab. It is recommended that for sites not doing finger stick HIV testing, blood for HIV serology and plasma archive are collected together, to limit venipuncture to a single blood draw. If a participant is subsequently found to be ineligible and is not enrolled, the plasma archive sample should be destroyed.
- Pelvic exam procedures must be performed in the sequence shown on the pelvic exam checklists at visits where a pelvic exam is required. For clinically indicated pelvic exams, procedures may be documented in the chart notes rather than the Pelvic Exam checklist. For CRF completion instructions, see Sections 3, 10, and 14.
- During study follow-up, it is recommended that behavioral assessment forms and ACASI questionnaires be administered prior to the delivery of HIV Prevention Options counseling.
- It is recommended that procedures for determining eligibility for continued product use be conducted early in the visit to ensure that these procedures are conducted in the event that the participant needs to abruptly leave the clinic, or is short of time.
- Ideally, self-collected vaginal swabs should be collected with the vaginal ring (from the previous visit) still in place, if applicable.
- As applicable, VRs should be removed immediately upon identification of conditions which require a hold or discontinuation. Otherwise, timing of VR removal depends on whether a pelvic exam is being conducted:
 - At follow-up visits *without* pelvic exams, it is recommended that participants are asked not to remove current vaginal ring (VR) until immediately prior to provision of a new VR for insertion. In the event that the participant needs to leave the clinic abruptly, she will already have a VR in place or eligibility for continued product use will have been determined.
 - At follow-up visits *with* pelvic exams, it is recommended that participants are asked not to remove current VR until immediately prior to the pelvic exam. Provision of a new VR for insertion should occur after the exam.

Note that the time of each study procedure does not need to be documented in order to demonstrate the order of visit procedures if this can be accomplished through other approaches. Acceptable alternatives include using a statement in the chart note or on visit checklists which verifies correct order was executed (e.g. “*Confirmed eligibility determination, all baseline behavioral assessments completed and plasma archive and vaginal swab samples collected. Participant opted to receive a VR, prescription for study product will now be completed and study product provided*”), or by documenting that procedures were conducted ‘per site SOPs’ which specify order. As always, *deviations* from SOPs should be explained in the chart notes. This applies to procedures listed above whose order is required (first five bullet points); the order of procedures listed above as ‘ideal’ or ‘recommended’ does not need to be demonstrated in source documentation.

3.4.3 Laboratory

Each lab test must have a defined source document which is the first place the result is recorded or generated. Site laboratories will have a plan for the storage of these documents so that they are easily retrievable. See SSP Section 13 for more information on source documentation requirements for the lab.

3.4.4 Case Report Forms (CRFs)

The case report forms (CRFs) for this study are designed for use with the Medidata Rave data management system described in Section 14 of this manual. As shown in the source document SOP template, CRFs have been designed to be used as source whenever possible. Prior to study activation, **each study site will document the CRFs used as source as well as which CRFs are not used as source in its SOP for Source Documentation.** This SOP will also specify which CRFs will initially be completed in paper format or electronic format (eCRF). The specifications of this SOP must be followed consistently for all study participants. In the event that study staff are not able to record data directly onto forms designated as source documents, the following procedures should be undertaken:

- Record the data onto an alternative source document
- File the alternative source document into the participant's study chart
- Transcribe the data from the alternative source document onto the appropriate form and enter a note on the form stating the alternate source document used
- Write a chart note stating the relevant study visit date and the reason why an alternative source document was used

3.5 Protocol Deviations

In addition to the above, DAIDS requires that all protocol deviations be documented in participant records, along with efforts made to correct the deviations, and efforts made to prevent similar deviations in the future. The MTN Manual of Operational Procedures should be referenced for complete guidance on protocol deviations.

For MTN-025 the Protocol Deviation Log CRF will be used to document each protocol deviation. The Protocol Deviation Log CRF is completed and submitted to the SDMC for each reportable deviation identified. Missed visits are considered protocol deviations per the MTN policy, however these will *not* be captured on the Protocol Deviation Log CRF for HOPE (the Missed Visit CRF will capture this information instead). As corrective and preventive action plans are required components of protocol deviation documentation, it is important to ensure that chart notes or other source documentation documents the associated counseling that accompanies missed visits.

If a protocol deviation needs to be reported, but is not associated with a specific participant (e.g., study product exceeds storage temperature while at the pharmacy), a paper-based protocol deviation log should be completed, and scanned/mailed to the MTN-025 management team. **Note that these non-participant specific PTIDs are not entered into Medidata Rave.** Line through the PTID field and initial and date this change. Assign page numbers sequentially (as usual) when completing new PDLs using this PTID. Please contact the MTN-025 management team prior to submission of any non-participant specific protocol deviations.

If a protocol deviation related to a screening or pre-screening participant who is not yet in the Medidata Rave database occurs, a paper-based protocol deviation log should be completed. If this participant enrolls into HOPE, the CRF must be entered into the database. If the potential participant never enrolls into HOPE (i.e. screen failure), the paper CRF should be scanned/mailed to the MTN-025 CDMs.

If there is any question as to whether a deviation has occurred, or how it should be documented, the MTN Regulatory Department (mtnregulatory@mtnstopshiv.org) and MTN-025 Management Team should be contacted. Once the potential protocol deviation has been confirmed, the site will be contacted with this confirmation and the 7-day reporting requirement will begin. Once the CRF is submitted, the MTN Regulatory department or the study management team will follow up with the site regarding any next steps as needed.

It is recommended that sites report in an expedited manner to IRBs/ECs PDs that pose a potential safety risk to a participant(s) and those that could affect the integrity of the study according to the local IRBs/ECs' standard operating procedures and guidelines.

It is also recommended that a complete list of all PDs occurring at the site, including PDs not meeting immediate reporting standards noted above, be submitted to the local IRBs/ECs in accordance with their reporting policies. If a local IRB/EC does not have a specific reporting policy, MTN recommends that this be done at the time of IRB renewal submission, annually or semi-annually per local requirements. These listings will be provided by MTN to the sites on request. Sites should request these PD listings from SCHARP at least two weeks prior to the planned date of submission to their local IRBs/ECs.

Note that some protocol deviations will also be considered critical events (though some critical events may not be considered protocol deviations). Refer to the DAIDS Critical Event Manual and Policy for detailed guidance on the definition of critical events and reporting processes. These documents can be accessed on the MTN Website: <http://www.mtnstopshiv.org/node/4535>. The site OCSO Program Officer should be contacted with any questions related to critical events, including reporting requirements and procedures, preventive and corrective action plans, and critical events tracking questions.

3.6 Document Organization and Participant Confidentiality

Study staff must make every effort to store all study records securely and confidentially. Case history records must be stored in the same manner for all participants, in areas with access limited to authorized study staff only. Study staff are responsible for purchasing file folders, binders, storage cabinets, and any other equipment or supplies needed to properly store all records.

Study-related documentation collected during the screening process should be stored in a file folder/binder for each potential participant. All screening documentation — for potential participants who eventually enroll in the study as well as for those who do not enroll or “screen out” — must be maintained and available for monitoring throughout the study. This documentation also must be available for reference should participants present to the site for re-screening. For participants who enroll in the study, screening documentation should be transferred to a separate file folder/binder that will serve as participants' study notebook for the duration of their participation in the study.

All documents contained in participant case history records must bear a participant identifier, which generally will consist of either the participant identification number (PTID) or the participant name. The PTID should be used whenever possible to maximize participant confidentiality. As a best practice, it is recommended that records bearing names or other personal identifiers, such as locator forms and

informed consent forms, are stored separately from records identified by PTID. Any documents transferred or transmitted to a non-study site location must be identified by PTID only. Care should also be taken to only refer to participants by PTID in email communication when people outside of the CRS are included. Note this is particularly relevant in cases where participants are transferred between sites and members of the management team are cc'd on communication.

Regardless of whether the identifier on a particular document consists of the participant name or PTID, the original identifier may not be obliterated or altered in any way, even if another identifier is added. When necessary to maintain confidentiality, identifiers may be obliterated on copies of original source documents. For example, if medical records obtained from a non-study health care provider bear the participant's name, the original documents bearing the name must be stored unaltered with other study documents bearing the name. However, a copy of the original documents could be made, the PTID could be entered onto the copies, and then the participant name could be obliterated from the copies. Copies handled in this way could then be stored in participants' study notebooks and/or transferred or transmitted to non-study site locations.

All on-site databases and ACASI questionnaire data must be secured with password protected access systems. Any lists, appointment books, or other documents that link PTIDs to other participant identifiers (such as the PTID/Name Linkage Log) should be stored securely (locked cabinet/drawer if hard copy; password protected if electronic) and it is recommended in a location separate from individual participant records (that identify participant by either PTID or name). When in use, documents that link PTIDs to other participant identifiers should not be left unattended or otherwise accessible to study participants, other study clinic patients, or any other unauthorized persons.

3.7 Study Product Accountability, Chain of Custody, and Dispensing Documentation in the Pharmacy

Pharmacy staff will document the receipt and dispensing of each vaginal ring, and destruction of each unused vaginal ring. Separate accountability records must be maintained for product, per instructions provided in the MTN-025 Pharmacist Study Product Management Procedures Manual available from the MTN Pharmacist.

Pharmacy staff also will maintain in the study pharmacies a Participant-Specific Pharmacy Dispensing Record for all enrolled study participants, per instructions in the MTN-025 Pharmacist Study Product Management Procedures Manual. Study clinic staff will contribute to the documentation of product provision and chain of custody as described in Sections 4 and 9 of this manual.

The specifications related to document security and participant confidentiality described in protocol section 13.6 also apply to records maintained in the study pharmacies. All records must be stored securely in the pharmacies with access limited to authorized study pharmacy staff only.

The following essential documents should be maintained in study site pharmacies:

- Current MTN-025 Protocol
- Investigator's Brochure for Dapivirine Vaginal Ring: current version and any subsequent updates
- Current FDA Form 1572
- Current list of authorized prescribers and staff authorized to sign Study Product Request Slips (names and signatures)
- Pharmacy Establishment Plan (DAIDS PAB approved or MTN Core Pharmacist approved)

- MTN-025 Pharmacist Study Product Management Procedures Manual and applicable SOPs for investigational study product management, dispensation and accountability
- MTN-025 SOP for product Chain of Custody
- MTN-025 product shipping and receipt documentation, product storage temperature logs, and investigational product accountability records
- MTN-025 participant-specific records (including prescriptions and ring request slips, participant-specific dispensing record, record of receipt of participant study product and documentation of unused product returns)
- MTN-025 monitoring visit reports
- MTN-025 communications with site clinic staff, communications with the MTN Pharmacist, IPM Clinical Supply Coordinator and/or Catalent (product distributor)
- MTN-025 communications with the MTN LOC and/or the MTN SDMC or other MTN-025 communications or locally-required administrative, operational, and/or regulatory documentation

3.8 Study Product Accountability and Disposal Documentation in the Clinic

Clinic staff will document the number of vaginal rings provided to the participant and the number of used and unused rings collected from the participant. Of the rings collected, it will be documented whether they were sent to the laboratory for storage or disposed of in the clinic (used rings), or sent to pharmacy for quarantine (unused rings). Clinic Participant-Specific Ring Accountability Log will be used to capture this information. Used Ring Destruction Log will be used to record the ultimate destruction of rings collected for disposal; expect this to be rare. Both logs are found on the MTN-025 website (<http://www.mtnstopshiv.org/node/7330>) and must be maintained in hard copy.

3.9 Record Retention Requirements

All study records must be maintained for at least two years following the date of marketing approval for the study product for the indication in which they were studied. If no marketing application is filed, or if the application is not approved, records must be retained for two years after the US Food and Drug Administration is notified that the Investigational New Drug application for the product(s) is discontinued.

All records must be retained on-site throughout the study's period of performance, and for at least three years after completion or termination of the study. Study product records must be stored in site pharmacies, with access limited to authorized study pharmacy staff only. DAIDS will provide further instructions for long-term storage of study records after the study is completed. Study records should not be re-located to an off-site location or destroyed without prior approval from DAIDS.

3.10 Translation Procedures

Per Sections 11.2 and 11.14 of the MTN Manual of Procedures (MOP), all study materials that are read verbatim or provided to the participant must be translated into local language, back-translated, and reviewed by FHI 360 or other members of the study management team as appropriate. Participant materials include the informed consent forms and enrollment comprehension checklist, interviewer-administered CRFs, ACASI, qualitative interviews, and other study materials developed for participant use (e.g. fact sheets, instruction sheets, community education tools, etc.).

Site teams are responsible for establishing a site-specific translation SOP that should minimally contain the following elements:

- Description of the translation and back-translation process and the quality control of it
- Who is responsible for conducting each step of this process (and whether is occurring on-site staff or through a contracted group)

All staff members involved in the translation and back-translation process should ensure that language fluency is documented on their CV on file at the research site and this responsibility is assigned per the site Delegation of Authorities Log. A standard Certificate of Translation should be issued for each set of translations conducted, indicating the specific documents that were translated (with version number/date as appropriate) as well as the individual conducting the translation. It is recommended that as part of translation procedures, staff members who will be responsible for utilizing the translated study materials review and/or pilot use of the tool to confirm translations are understandable in the context they will be used.