Section 3. Documentation Requirements

Study staff 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 — commonly referred to as participant "case history records" — for MTN-013/IPM 026.

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 including MTN-013/IPM 026. Based on this DAIDS Policy, the documentation listed below must be maintained for the MTN-013/IPM 026 study. Although all required documentation must be available for inspection at any time, all documents need not be stored together in one location.

Note: When required documents are modified or updated, the original and all modified or updated versions must also be retained.

Section Appendix 3-1 presents a suggested essential documents filing structure for MTN-013/IPM 026. 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 Section Appendix 3-1 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, Figure 3-1.

- To facilitate routine inspection by study monitors, certain laboratory-related essential documents should be stored in the main study essential documents files/binders (see Section Appendix 3-1). Other lab-related essential documents (e.g., lab SOPs) may be filed in site laboratories.

- The suggested filing structure assumes that MTN-013/IPM 026 participant case history records will be stored separately from the other essential documents listed in Section Appendix 3-1. Section 3.2 below provides information on the required contents of these records. The suggested filing structure also assumes that the Screening and Enrollment Log, Participant Name-ID Number Link Log, and Randomization Envelope Tracking Record will be stored in the study clinic or data management area and not necessarily with the other essential documents listed in Section Appendix 3-1.

3.2 Participant Case History Documentation

Study sites must maintain adequate and accurate participant case history records containing all information pertinent to MTN-013/IPM 026 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.

3.2.1 Case History Contents

Participant case histories should contain all of the following elements:

- Basic participant identifiers
- Documentation that the participant provided written informed consent to screen for and participate in the study prior to the conduct of any screening or study procedures, respectively
- Documentation that the participant met the study's eligibility criteria
- A record of the participant's random assignment
- A record of the participant's exposure to the investigational study products
- A record of all contacts, and attempted contacts, with the participant.
- A record of all procedures performed by study staff during the study
- 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)

In addition to the above, DAIDS requires that all protocol deviations be documented in participant records, along with reasons for the deviations, efforts made to correct the deviations, and efforts made to prevent similar deviations in the future. Study sites also must report protocol deviations per Section 16.4 of the MTN MOP using the designated Protocol Deviation Form. The MTN Protocol Deviation Form is posted on the MTN website at http://www.mtnstopshiv.org/node/187. Site staff should submit a draft form for review and comment by the study management team (mtn013mgmt@mtnstopshiv.org). The management team may consult members of the protocol team to help to reach a consensus regarding whether or not the event should be reported as a protocol deviation. They will also review the content of the protocol deviation form to ensure the complete and accurate prior to broader distribution. Once the form is finalized, it should be distributed to the distribution list (mtn013protocoldeviations@mtnstopshiv.org) which includes the following: Protocol Chair, CORE Clinical Research Manager, SDMC Project Manager, NL representative, MTN Pharmacist, IPM Project Manager, OCSO Program Officer, and the DAIDS Medical Officer.

3.2.2 Concept of Source Data and Source Documentation

The International Conference on Harmonization Consolidated Guidance for Good Clinical Practice 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. 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 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.

For MTN-013/IPM 026, participant case history records should consist of the following source documents:

- Narrative chart notes
- Randomization envelopes and prescriptions documenting participants' random assignments
- Pharmacy investigational product dispensing and chain of custody records (maintained in the study site pharmacy)
- Visit checklists and/or other site-specific procedural flow sheets
- Local laboratory testing logs and result reports
- DataFax and Non-DataFax forms provided by the MTN Statistical and Data Management Center (SDMC)
- Other source documents (e.g., site-specific worksheets, non-study medical records)

As a condition for study activation, each study site must establish an SOP for Source Documentation that specifies the use of the above-listed documents as source documents. Although it is the responsibility of each site to determine the most appropriate source document for each required case history element, Section Appendix 3-2 provides a guide that sites may follow for this study. Supplemental information on the use of chart notes, visit checklists, and forms provided by the MTN SDMC is provided below. Detailed information on proper completion, maintenance, and storage of participant randomization and product dispensing documentation is provided in Sections 4, 6, and 9 of this manual. Detailed information on proper completion of DataFax and Non-DataFax forms provided by the MTN SDMC is provided in Section 13 of this manual.

Chart Notes: Study staff must document every contact with a study participant in a signed and dated chart note specifying the following information when necessary to document adherence to protocol requirements:

- Visit date and time at which a contact takes place or at which a particular procedures take place
- Visit type (scheduled, interim, etc)
- Purpose of the visit and location of the contact or (phone, in-clinic etc)
- General status of the participant at the time of the visit

Chart notes also should be used to document the following:

- The screening and enrollment informed consent processes
- Procedures performed that are not recorded on other source documents
- 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
- Protocol deviations that are not otherwise captured on other source documents

Visit Checklists: The checklists in Section 7 of this manual are convenient tools which serve as source documentation and fulfill the requirement of documenting study procedures performed with each study participant. These checklists alone may not be sufficient for documenting all procedures. Chart notes also may be required to document the content of counseling sessions and/or other in-depth discussions with participants (e.g., related to adherence to protocol requirements). For example, chart notes may be required to document procedures performed at unscheduled study visits and/or to explain why procedures in addition to those listed on a checklist were or were not performed.

DataFax and Non-DataFax Forms Provided by the MTN SDMC: The case report forms (CRFs) for this study are designed for use with the DataFax data management system described in Section 13 of this manual. The SDMC will provide these forms as well as several study-specific non-DataFax forms to each site. See Section Appendix 3-4 for a listing of all DataFax and non-DataFax forms to be provided for this study.

As shown in Section Appendices 3-5 and 3-6, many of the DataFax and non-DataFax forms provided by the SDMC have been designed to serve as source documents. Each study site must document the forms that routinely will be used as source documents in its SOP for Source Documentation. 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 forms designated as source documents, the following procedures should be undertaken:

- Record the data onto an alternative source document
- Enter 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
- Enter a chart note stating the relevant study visit date and the reason why an alternative source document was used

3.2.3 Document Organization

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 — 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 then be transferred to a separate file folder/binder which 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. Records that bear names or other personal identifiers, such as locator forms and informed consent forms, should be stored separately from records identified by PTID. Any documents transferred or transmitted to a non-study site location — including DataFax forms— must be identified by PTID only.

Note: 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 CASI questionnaire data must be secured with password protected access systems. Any lists, appointment books, or other documents that link PTIDs to other participant identifiers should be stored securely in a location separate from records identified by participant name only and separate from records identified by PTID only. 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.

As a condition for study activation, each study site must establish an SOP for Data Management. This SOP minimally should contain the following elements:

- Procedures for assigning PTIDs, linking PTIDs to participant names, and storing the name-PTID link log
- Procedures for establishing participant files/charts/notebooks
- During-visit participant chart and case report form review procedures
- Post-visit participant chart and case report form review procedures and timeframes
- Data transmission procedures, including timeframes, case report form storage locations before and after faxing, and mechanisms for identifying when forms have been transmitted
- CASI data collection, back-up, and transmission procedures, including timeframes, CASI equipment storage locations, and mechanisms for identifying when questionnaires have been transmitted
- Procedures for resolving/troubleshooting questionnaire issues
- Procedures for resolving data quality control notes from the SDMC
- Storage locations for blank case report forms
- Storage locations for documents identified by participant names or other personal identifiers
- Storage locations for documents identified by PTID

- Confidentiality protections
- Other ethical and human subjects considerations
- Staff responsibilities for all of the above (direct and supervisory)
- QC/QA procedures related to the above (if not specified elsewhere)

3.3 Study Product Accountability, Chain of Custody, and Dispensing Documentation

Pharmacy staff will document the receipt, dispensation, resupply, and final disposition of each investigational product used in the study. Separate accountability records must be maintained for product, per instructions provided in the MTN-013/IPM 026 Pharmacy Instruction Manual available from the MTN Pharmacist.

Pharmacy staff also will maintain in the study pharmacies randomization materials for all enrolled study participants and product dispensation records for all participants, per instructions in the MTN-013/IPM 026 Pharmacy Instruction Manual. Study clinic staff will contribute to the documentation of product dispensation and chain of custody as described in Sections 4, 6, and 9 of this manual.

The specifications related to document security and participant confidentiality described in Section 3.2 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.

To preserve the double blinding of participants' random assignments, neither study clinic staff nor study participants will be provided access to product-related documentation maintained in the study pharmacies. Pharmacy staff will provide copies of some participant-specific documentation maintained in the study pharmacies to clinic staff as described in Sections 6 and 9 of this manual, but under no circumstances will documentation released from the pharmacy include participants' product dispensing records or other information related to participants' random assignments. The following essential documents should be maintained in study site pharmacies:

The essential documents listed in Figure 3-1 below should be maintained in study site pharmacies.

Figure 3-1
MTN-013/IPM 026 Essential Documents Maintained in Study Site Pharmacies

- Current MTN-013/IPM 026 Protocol
- Investigator's Brochure for Dapivirine/Maraviroc 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-013/IPM 026 Pharmacy Instruction Manual and applicable SOPs for investigational study product management, dispensation and accountability
- MTN-013/IPM 026 SOP for product Chain of Custody
- MTN-013/IPM 026 PTID list (provided by the MTN SDMC)
- MTN-013/IPM 026 product shipping and receipt documentation, product storage temperature logs, and investigational product accountability records
- MTN-013/IPM 026 participant-specific records (including prescriptions, pharmacy randomization envelope, documentation of unused product returns, product dispensing and re-issuing records)
- MTN-013/IPM 026 monitoring visit reports
- MTN-013/IPM 026 communications with site clinic staff, communications with the MTN Pharmacist and/or the IPM Clinical Supply Coordinator
- MTN-013/IPM 026 communications with the MTN CORE and/or the MTN SDMC or other MTN-013/IPM 026 communications or locally-required administrative, operational, and/or regulatory documentation

3.4 Record Retention Requirements

All study records must be maintained for at least two years following the date of marketing approval for each of the three study products 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, until the study is unblinded. 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.

Section Appendix 3-1
Suggested Filing Structure for MTN-013/IPM 026 Essential Documents

File/Binder #1: MTN-013 Protocol and Current Informed Consent Forms

1. MTN-013/IPM 026 Protocol (including copy of signed and dated protocol signature page): Version 1.0 and any subsequent protocol Clarification Memos, Letters of Amendment, and Amendments issued after Version 1.0
2. Currently-approved (blank) MTN-013/IPM 026 Informed Consent Forms

File/Binder #2: Regulatory Authority Documentation (if applicable)

3. Regulatory Authority Correspondence/Authorization/Approval/Notification of Protocol (if applicable; if more than one regulatory authority has oversight responsibility for research performed at the study site, include subsections for each authority)

File/Binder #3A; 3B: IRB/EC Documentation for each applicable IRB [IRB/EC A]; [IRB/EC B]

4. FWA documentation for IRB/EC
5. Roster of IRB/EC (if available)
6. Relevant IRB/EC Submission Requirements/Guidelines/SOPs
7. IRB Correspondence for IRB/EC: File complete copies of all correspondence to and from the IRB/EC; include all enclosures/attachments for all submissions, even if copies of the enclosures/attachments are filed elsewhere; include all approval documentation.

File/Binder #4: Product Safety Information

8. Investigator's Brochure for Dapivirine/Maraviroc Vaginal Ring: current version and any subsequent updates
9. Product Safety Information/Reports/Memos

Notes:

- It is assumed that expedited adverse event reports will be stored in participant study notebooks.
- It is assumed that documentation of IRB/EC submission of above-listed documents (if applicable) will be maintained in the relevant IRB/EC Files/Binders (i.e., File/Binder #3A and #3B).

File/Binder #5: MTN-013/IPM 026 Study-Specific Procedures (SSP) Manual

10. Final version 1.0 (when available) and any subsequent updates

Notes:

- For this reference copy of the SSP Manual, do not discard out-dated pages or sections when updates are issued; retain all versions of all pages as a complete historical record. The SSP Manual contains reference versions of all study case report forms, therefore additional (blank) copies of the case report forms need not be stored elsewhere in the essential document files.

File/Binder #6: MTN-013/IPM 026 Study-Specific Standard Operating Procedures

11. Final approved version of each site specific SOP, and any subsequent updates to each

File/Binder #7: MTN-013/IPM 026 Staffing Documentation

12. FDA Form 1572 (copy of original and dated form submitted to the DAIDS Protocol Registration Office (PRO), and any subsequent updates)
13. Investigator of Record CV (copy of CV submitted to the DAIDS PRO; ensure that the CV is current prior to initiating the study; CVs should be signed and dated to document at least annual updating)
14. Financial Disclosure Forms (original signed and dated forms, and any subsequent updates)
15. Study Staff Roster (original submitted to MTN CORE for study activation, and any subsequent updates)
16. Study Staff Identification and Signature Sheet (if not combined with staff roster; original and any subsequent updates)
17. Study Staff Delegation of Duties (if not combined with staff roster; original and all updates)
18. CVs for Study Staff other than the IoR (ensure that all CVs are current prior to initiating MTN-013; it is recommended that CVs be signed and dated to document at least annual updating)
19. Study Staff Job Descriptions
20. Documentation of Study Staff Training

Section Appendix 3-1
Suggested Filing Structure for MTN-013/IPM 026 Essential Documents

File/Binder #8: Local Laboratory Documentation

21. Local Laboratory Certification(s), Accreditation(s) and/or Validation(s): file documentation current at time of study activation and all subsequent updates
22. Local Laboratory Normal Ranges: file documentation of relevant normal ranges for all protocol-specified tests current at time of study activation and all subsequent updates
23. Laboratory Manager CV (or cross-reference to CV contained in File/Binder #7)

Note:

- It is recommended that a cross-reference be included in this file/binder specifying the storage location(s) of other lab-related essential documents filed in the local lab(s).

File/Binder #9: Monitoring Visit Documentation

24. Monitoring Visit Log
25. Initiation and Monitoring Visit Reports and Documentation of Response to Visit Findings

File/Binder #10: Documentation of Other MTN Site Visits

26. MTN CORE Site Visit Reports and Documentation of Response to Visit Findings
27. MTN SDMC Site Visit Reports and Documentation of Response to Visit Findings
28. MTN Network Lab Site Visit Reports and Documentation of Response to Visit Findings
29. Other Site Visit Reports and Documentation of Response to Visit Findings

File/Binder #11: Study-Related Sponsor Communications

30. Study-Related Communications to and from DAIDS
31. Communications to and from DAIDS RSC (includes copies of all submissions to the DAIDS PRO)

Notes:

- Communications related to individual MTN-013/IPM 026 study participants will be filed in individual participant study records.
- Product-related communications with MTN Pharmacist (and its contractors) will be stored in the study pharmacy.

File/Binder #12: Other Study-Related Communications

32. Study-Related Communications to and from MTN CORE
33. Study-Related Communications to and from MTN SDMC
34. Study-Related Communications to and from MTN Network Lab
35. Other Study-Related Communications

Notes:

- Communications related to individual MTN-013/IPM 026 study participants will be filed in individual participant study records.
- Product-related communications with MTN Pharmacist (and its contractors) will be stored in the study pharmacy.

File/Binder #13: Study Site Staff Meeting Documentation

36. MTN-013/IPM 026 Staff Meeting Agendas, Participant Lists/Sign-In Sheets, and Summaries

File/Binder #14: Conference Call Documentation

37. Protocol Team Conference Call Summaries
38. Community Working Group Conference Call Summaries
39. Summaries of Other Conference Calls

File/Binder #15: DAIDS and Other Reference Documentation

40. DAIDS Protocol Registration Policy and Procedures Manual
41. Manual for Expedited Reporting of Adverse Events to DAIDS
42. US Regulations Applicable to Conduct of MTN-013/IPM 026 (45 CFR 46; 21 CFR 50, 54, 56, and 312)
43. Any other relevant manuals or reference documents

File/Binder #16: Site-Specific Study Activation Documentation

44. Site-Specific Study Activation Notice and supporting documentation

Section Appendix 3-2
Guide to Required Case History Elements and Source Documents for MTN-013/IPM 026

Required Case History Element	Source Documents
Basic participant identifiers	Locator form; Demographics form.
Documentation that the participant provided written informed consent to screen for and participate in the study.	Signed and dated informed consent forms; signed and dated chart notes stating that informed consent was obtained prior to initiating study procedures.
Documentation that the participant met the study eligibility criteria.	MTN-013/IPM 026 Eligibility Checklist.
A record of the participant's random assignment.	MTN-013/IPM 026 randomization envelope tracking records; MTN-013/IPM 026 randomization envelope; MTN-013/IPM 026 prescription.
A record of the participant's exposure to the investigational study products (Participants in Group A).	MTN-013/IPM 026 Prescription, MTN-013/IPM 026 Vaginal Ring Request Slip, MTN-013/IPM 026 site-specific pharmacy dispensing record; dispensed product chain of custody logs, visit checklists.
A record of all contacts, and all attempted contacts, with the participant.	Signed and dated chart notes, and/or other worksheets or site-specific documents if designated in site SOPs.
A record of all procedures performed by study staff.	Completed visit checklists; signed and dated chart notes detailing (i) procedures performed in addition to those contained on the checklist and/or (ii) the reason why procedures contained on the checklist were not performed.
Information on the participant's condition before, during, and after the study.	All documents listed above; Pelvic Exam Ring Assessment form; Follow-Up Visit form; Ring Adherence form; Medical History Log; Adverse Experience Log; HIV test results form; Product hold/discontinuation Log form; Pregnancy Report form; Pregnancy Outcome form; Genital Bleeding Assessment form; local lab logs and result reports from the local lab[§]; results of information pertinent to the study obtained from non-study sources; signed and dated chart notes.

Section Appendix 3-3
MTN-013/IPM 026 DataFax and Non-DataFax Forms

DataFax Forms	Non-DataFax Forms
Adverse Experience Log	Enrollment Behavioral Eligibility
Cervical Biopsy Weights	Genital Bleeding Assessment
Cervical Ectopy	MTN-013/IPM-026 LDMS Specimen Tracking Sheet
Concomitant Medications Log	MTN-013/IPM-026 LDMS Specimen Tracking Sheet – Enrollment and Day 28 Blood PK
Demographics	Physical Exam
Eligibility Criteria	Pelvic Exam Diagrams
End of Study Inventory	Screening Behavioral Eligibility
Enrollment	
Follow-up CASI Tracking	
Follow-up Visit	
HIV Test Results	
Interim Visit	
Laboratory Results	
Missed Visit	
Pelvic Exam	
Pelvic Exam Ring Assessment	
Pharmacokinetics Specimens	
Pre-Existing Conditions	
Pregnancy Report	
Pregnancy Outcome	
Product Hold/Discontinuation Log	
Ring Adherence	
Specimen Storage	
Test Tear Strips Weights	
Termination	

Section Appendix 3-4
Use of MTN-013/IPM 026 DataFax Forms as Source Documents
(Forms listed in alphabetical order)

Form Name	Acronym	Is Form Source?	Comments
Adverse Experience Log	AE-1		Form may be source for all items.
Cervical Ectopy	CE-1		Form may be source for all items.
Cervical Biopsy Weights	CBW-1		Form may be source for all items.
Concomitant Medications	CM-1		Form may be source for all items.
Demographics	DEM-1, DEM-2, DEM-3	Yes	Form is source for all items as participant responses are recorded directly onto the form
Eligibility Criteria	ECI-1		Form may be source for item 1. Storage/Future Testing of Specimens informed consent form is source for item 2.
End of Study Inventory	ESI-1	No	All items are based on source data recorded on other documents.
Enrollment	ENR-1	No	The applicable Informed consent form is source for items 1 and 2. The MTN-013/IPM-026 Randomization Envelope Tracking Record is source for items 3-5. The prescription is source for item 6. The Enrollment Visit checklist is source for items 7 and 8.
Follow-up CASI Tracking	FCT-1		Form may be source for all items. Visit checklists may also be source – site to choose.
Follow-up Visit	FV-1		Testing log is source for item 1. Form may be source for items 2-5.
HIV Test Results	HTR-1		Local laboratory report(s) are source for items 1-3. Form may be source for item 4.
Interim Visit	IV-1		Form may be source for items 1, 4, and 5. Form is source for item 2. Testing log is source for item 3.
Laboratory Results	LR-1, LR-2		Local laboratory result reports are source for all lab values. Form may be soure for all non-lab value items (i.e. severity grade, etc.).
Missed Visit	MV-1		Form may be source for all items.
Pelvic Exam	PE-1, PE-2		Pelvic Exam Diagrams is source for items 1 and 1a. Form may be source for items 2-6.
Pelvic Exam Ring Assessment	PER-1		Form may be source for all items.
Pharmacokinetics Specimens	PKS-1		Form may be source for all items. Note to site – if the Physical Exam or other sheet will be used as source for item 1 (weight), specify here.
Pre-Existing Conditions	PRE-1	No	Medical History Log sheet and other study documents are source for all items. Note to site – if you are using something different than the Medical History Log sheet provided, specify what will be source.
Pregnancy Outcome	PO-1, PO-2		Form may be source for all items if medical records are not available (and data are based on participant self-report). If medical records are obtained, then they will be source for as many items as possible.

Section Appendix 3-4
Use of MTN-013/IPM 026 DataFax Forms as Source Documents
(Forms listed in alphabetical order)

Form Name	Acronym	Is Form Source?	Comments
Pregnancy Report	PR-1		Form may be source for all items.
Product Hold Discontinuation Log	PH-1		Form may be source for all items.
Ring Adherence	RA-1		Form may be source for all items.
Specimen Storage	SS-1		Form may be source for all items.
Tear Test Strip Weights	TTW-1		Form may be source for all items.
Termination	TM-1	No	All items are based on source data recorded on other documents.

Note: For forms where the site indicates that they will use the form as source, site should update "Comments" as needed to indicate which form items will be used as source. Site should replace all "may be used as source" to "will be used as source" or "will not be used as source" as applicable, to match the previous column. IF blank, site should complete to indicate whether form will be used as source at their site.

Section Appendix 3-5
Use of MTN-013/IPM 026 Non-DataFax Forms as Source Documents
(Forms listed in alphabetical order)

Form Name	Is Form Source?	Comments
Enrollment Behavioral Eligibility	Yes	Form is source for all items as participant responses are recorded directly onto the form.
Genital Bleeding Assessment		Form may be source for all items.
MTN-013/IPM-026 LDMS Specimen Tracking Sheet		Form may be source for all items.
MTN-013/IPM-026 LDMS Specimen Tracking Sheet: Enrollment and Day 28 Blood PK		Form may be source for all items.
Pelvic Exam Diagrams		Form may be source for all items.
Physical Exam		Form may be source for all items.
Screening Behavioral Eligibility	Yes	Form is source for all items as participant responses are recorded directly onto the form.