Section 2. Documentation Requirements

Study staff members are responsible for the 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-024/IPM 031.

2.1 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 on the MTN-024/IPM 031 webpage (http://www.mtnstopshiv.org/node/4924). The suggested filing structure assumes that participant research records will be stored separately from the other essential documents. Section 2.2 below provides information on the required contents of these records. Study sites are not required to adopt this filing 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, which may be 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 2.3.
- 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 standard operating procedures [SOPs]) may be filed in site laboratories.
- The MTN-024/IPM 031 PTID-Name Linkage Log and Randomization Tracking Record must be maintained in hard copy throughout the duration of the trial. The suggested filing structure 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.

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

2.2 Participant Research Records

MTN-024/IPM 031 study sites must maintain adequate and accurate participant research records containing all information pertinent to 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.

2.2.1 Concept of Source Data and Source Documentation

The International Conference on Harmonisation 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 (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.

2.2.2 Required Source Documentation

For MTN-024/IPM 031, 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 screening or study procedures, respectively
- Documentation that the participant met the study's eligibility criteria
- Randomization tracking records and prescriptions documenting participants' random assignment
- A record of the participant's use of the investigational study product
- Pharmacy investigational product dispensing and chain of custody records (maintained in the study site pharmacy), as well as 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.
- DataFax and Non-DataFax case report forms (CRFs) and other forms provided by the MTN Statistical and Data Management Center (SDMC)
- 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 recommended source for specific study procedures has been specified in Appendix 2-1. 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 3 and 6 of this manual, and the MTN-024/IPM 031 Pharmacist Study Product Management Procedures Manual. Detailed information on proper completion of CRFs is provided in Section 11 of this manual.

2.2.2.1 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 when necessary to document adherence to protocol requirements:

- 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 should also be used to document the following:

- The screening and enrollment 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 or to retrieve unreturned study product.

2.2.2.2 Visit Checklists: Visit checklists are convenient tools designed to guide site staff in proper study procedures and may serve as source documentation if completed appropriately. These checklists alone may not be sufficient for documenting all procedures, but can be used to indicate that the procedure was completed. Visit checklist templates are available on the MTN-024/IPM 031 website under Study Implementation Materials.

Instructions for completing visit checklists in accordance with these requirements are as follows:

- 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, note the screening attempt number. Participants are allowed two screening attempts.

- The “Required at visits” column indicates when the item is required 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. Bracketing procedures which are consecutive and all done on the same date is also acceptable.

- If a procedure listed on the checklist is not performed, enter "ND" for "not done" beside the item and record the reason why on the checklist or in chart notes (; initial and date this entry.

The sequence of procedures presented on the visit checklists is a suggested ordering. In consultation with the MTN CORE (FHI 360), site staff are encouraged to modify the checklists to maximize the efficiency of site-specific study operations. Sites may alter the sequence of procedures, with the following exceptions:

- Informed consent must be obtained before any study procedures are performed. Study visit procedures are listed in protocol Sections 7.2-7.4.

- On the day of enrollment, random assignment must take place after final confirmation and verification of eligibility, administration of the Vaginal Practices CRFs, Baseline Computer Assisted Self-Interview (CASI) Questionnaire, and collection of blood for plasma archive.

- Pelvic exam procedures must be performed in the sequence shown on the pelvic exam checklist.

- Behavioral assessment forms and CASI questionnaires should be administered prior to the delivery of HIV and adherence 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.

- VRs should be removed immediately upon identification of conditions that require a hold or discontinuation. Otherwise, timing of VR removal depends on when the pelvic exam is conducted. At follow-up visits, clinicians should not remove current VR until immediately prior to the pelvic exam. Provision of a new VR for insertion should occur after the exam.

2.2.2.3 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 10 for more information on source documentation requirements for the lab.

2.2.2.4 **Case Report Forms (CRFs)**: See Section 11 of this manual for further details regarding the use of case report forms (CRFs) with the DataFax data management system. As shown in Appendix 2-2, 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. 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

2.2.3 Protocol Deviations

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

For MTN-024/IPM 031 the Protocol Deviation Log CRF will be used to document each protocol deviation with a few exceptions. Missed visits are considered protocol deviations per the MTN policy; however these will ***not*** be captured on the Protocol Deviation Log CRF. The Missed Visit CRF will capture this information instead. Protocol deviations related to study product adherence or failure to return the used ring to the clinic will be captured via the Ring Adherence CRF and Ring Collection/Insertion CRF, respectively. Like all CRFs, completed Protocol Deviation Log CRFs are faxed to the SDMC and will be filed in the participant's study binder.

Corrective and preventive action plans are required components of protocol deviation documentation. It is important to ensure that chart notes or other source documentation include any associated counseling that was done to address the protocol deviation (i.e. counseling on the importance of retention for missed visit deviations, study product non-adherence or failure to bring the used study product to the clinic visit). Note that the actions documented are not required to be completed in order to report the deviation to SCHARP. The Protocol Deviation Log page should be transmitted to SCHARP once the CRF is completed, even if all of the actions/plans are still in-progress.

Protocol deviations should be reported within 7 days of site awareness. If there is a question as to whether a deviation has occurred, or how it should be documented, the MTN Regulatory Department should be contacted at mtnregulatory@mtnstopshiv.org. 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 faxed, the MTN Regulatory Department will follow up with the site if any clarifications or additional information on the CRF is needed.

It is recommended that a complete list of all PDs occurring at the site 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, the MTN recommends that this be done at the time of IRB renewal submission, annually or semi-annually per local requirements. These listings may be provided by the MTN Regulatory Department to the sites upon request.

Note that some protocol deviations will also be considered critical events. Refer to the DAIDS Critical Event Policy and Critical Event Manual for detailed guidance on the definition of critical events and reporting process.

2.2.4 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. Any documents transferred or transmitted to a non-study site location — including DataFax forms— 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 site are included.

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.

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 (locked cabinet/drawer if hard copy; password protected if electronic). 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.

2.3 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 the quarantine or storage of each unused vaginal ring. Separate accountability records must be maintained for product, per instructions provided in the MTN-024/IPM 031 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-024/IPM 031 Pharmacist Study Product Management Procedures Manual. Study clinic staff will contribute to the documentation of product dispensation and chain of custody as described in Sections 3 and 6 of this manual.

The specifications related to document security and participant confidentiality described in Section 2.2.4 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 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. The following essential documents should be maintained in study site pharmacies:

- Current MTN-024/IPM 031 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 Pharmacist approved)
- MTN-024/IPM 031 Pharmacist Study Product Management Procedures Manual and applicable SOPs for investigational study product management and Chain of Custody
- MTN-024/IPM 031 product shipping and receipt documentation, product storage temperature logs, and investigational product accountability records
- MTN-024/IPM 031 participant-specific records (including prescriptions and ring request slips, randomization tracking record, participant-specific dispensing record, record of receipt of participant study product and documentation of unused product returns)
- MTN-024/IPM 031 monitoring visit reports
- MTN-024/IPM 031 communications with site clinic staff, communications with the MTN Pharmacist, IPM Clinical Supply Coordinator and/or product distributor
- MTN-024/IPM 031 communications with the MTN CORE and/or the MTN SDMC or other communications or locally-required administrative, operational, and/or regulatory documentation

2.4 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, 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 2-1
Source Documentation of Study Procedures

Source documents listed are recommended, but site should specify actual source document as needed in the Source Documentation SOP.

Evaluation/Procedure	Source Document(s)
ADMINISTRATIVE AND REGULATORY	
Obtain informed consent	**Signed and Dated Informed Consent form** **Informed Consent Coversheet (or chart note)** **Informed Consent Comprehension Checklist**
Assign a unique Participant Identification (PTID) number	**MTN-024/IPM 031 PTID-Name Linkage Log**
Assess and/or confirm eligibility	**Eligibility Criteria CRF (item 1)** **Screening Behavioral Worksheet** **Enrollment Behavioral Worksheet**
Collect/review/update locator information	Site locator document (collect/update) Visit checklist
Randomization	**MTN-024/IPM 031 Randomization Tracking Record**
Provide reimbursement	Visit checklist, site-specific reimbursement log, and/or chart note
Schedule next visit	Visit checklist and/or chart note
BEHAVIORAL	
Protocol adherence counseling	Chart note, site-specific counseling worksheet or Protocol Adherence Counseling Worksheet
Product adherence counseling	Chart note, site-specific counseling worksheet or Ring Use Adherence Key Messages Worksheet
HIV/STI risk reduction counseling	Chart note, site-specific counseling worksheet or HIV/STI Risk Reduction and Male Condom Counseling Worksheet
HIV pre- and post-test counseling	Chart note, site-specific counseling worksheet or HIV Pre/Post Test Counseling Worksheet
Behavioral assessment includes sexual activity, condom use, and intravaginal practices	CASI Baseline and Follow-up Questionnaires Completed interviewer-administered CRFs: **Vaginal Practices** **Study Approved Lubricant Use Log** CASI completion documented on: **Enrollment and Follow-up CASI Tracking CRFs**
Product adherence assessment	**Ring Adherence CRF**
Social harms assessment	Chart Note
CLINICAL	

Medical and menstrual history	**Pre-existing Conditions CRF** (all baseline conditions including clinical evaluations will be summarized here) **Adverse Experience Log CRF** (all follow-up conditions including abnormal findings from clinical evaluations will be documented on this CRF) Chart Notes *Source documentation for participant reported medical/menstrual history:* **MTN-024/IPM 031 Baseline Medical History Questions** and **Screening Menstrual History form** Chart Notes
Concomitant medications	**Concomitant Medications Log CRF**
Physical examination	**Physical Exam CRF**
Pelvic exam	**Pelvic Exam Diagrams** **Pelvic Exam CRF**
Disclose available test results	Chart note and/or visit checklist
Record/update AEs	**Adverse Experience Log CRF** Chart note
Treat or prescribe treatment for UTIs/RTIs/STIs or refer for other findings	Chart notes, prescription and/or referral documentation
LABORATORY	
hCG	Site-specific lab requisition form Site testing log/results report
Dipstick UA/Urine culture (if indicated)	Site-specific lab requisition form Lab result report
Urine NAAT for GC/CT	Site-specific lab requisition form Lab result report
HIV-1 Serology	Site-specific lab requisition form Site testing log/results report Lab result report HIV Results CRF
CBC with platelets	Site-specific lab requisition form Lab result report Safety Laboratory Results CRF
Serum Chemistries	Site-specific lab requisition form Lab results report Safety Laboratory Results CRF
FSH	Site-specific lab requisition form Site testing log/results report (rapids) Lab results report
Syphilis serology	Site-specific lab requisition form Site testing log/results report Lab result report
Plasma archive	**Enrollment CRF**

Rapid test for Trichomonas	Site-specific lab requisition form/ Lab result report Site testing log/results report STI Results CRF
Herpes lesion testing (if clinically indicated)	Site-specific lab requisition form/ Lab result report Site testing log/results report
Vaginal fluid (for pH)	Site testing log/results report, chart note, visit checklist STI Test Results CRF
KOH wet mount for candidiasis (if clinically indicated)	Site testing log/results report/ Lab result report
Vaginal fluid (for NAAT for GC/CT)	Site testing log/results report, chart note, visit checklist STI Test Results CRF
Saline wet mount for BV (if clinically indicated)	Site-specific lab requisition form/ Lab result report Site testing log/results report
Blood (for PK)	Pharmacokinetics CRF
Vaginal quantitative culture	Specimen Storage CRF
Gram stain collection	Specimen Storage CRF
Pap smear interpretation	Site testing log/results report/ Lab result report
Vaginal fluid (for PK subset)	Pharmacokinetics CRF
Cervical biopsies (for Intensive PK subset)	Pharmacokinetics CRF
Cytobrush collection (for biomarkers) (Case and Pitt only)	Specimen Storage CRF
STUDY PRODUCT/ SUPPLIES	
Provision of study specified condoms	Site-specific counseling worksheets or visit checklist
Provision of study VR instructions	Chart notes or Visit checklist or site-specific counseling worksheet
Provision of one study VR for insertion with amber zip bag	**Ring Collection/Insertion CRF** (Follow-up) **Clinic Study Product Accountability Log** Chart Note and/or Visit Checklist
Participant or clinician/designee to remove used study VR	**Ring Collection/Insertion CRF** Chart note or Visit checklist
Exam(s) by clinician to check VR placement	Chart note or Visit checklist
Collection of used study VR	**Ring Collection/Insertion CRF** **Clinic Study Product Accountability Log**
OTHER	
Protocol Deviations	**Protocol Deviation Log CRF**
A record of all contacts, and attempted contacts, with the participant	Missed Visit CRF Site-specific contact/outreach/retention logs and/or chart notes
A record of all procedures performed by study staff during the study	Visit checklists, chart notes, and/or other site-specific flow sheets
Participant Demographics	**Demographics CRF**
Staff-initiated Study Product Holds and Permanent Discontinuations	**Clinical Product Hold/Discontinuation Log CRF**

Section Appendix 2-2
CRFs Used as Source Documents

Unless otherwise noted in the Comments column, the CRF is source for all form items.

CRF Name	CRF Acronym	Comments
Adverse Experience Log	AE-1	Form may be source for all items.
Clinical Product Hold/Discontinuation Log	PH-1	Form may be source for all items.
Concomitant Medications Log	CM-1	Form may be source for all items.
Demographics	DEM-1	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. Eligibility Checklist and/or Screening and Enrollment Log may be source for all items.
Enrollment	ENR-1	The informed consent form should be source for items 1 and 2. Form may be source for item 3 (or lab requisition). The Randomization Envelope and Prescription should be source for items 4-6. This form may be source for item 7 and 8.
Follow-up CASI Tracking	FCT-1	Form may be source for all items.
Missed Visit	MV-1	Form may be source for all items.
Pelvic Exam	PE-1	Form may be source for all items except item 3. AE Log should be source for item 3.
Pelvic Exam Diagrams	N/A	Form may be source for all items.
Pharmacokinetics	PK-1	Form may be source for all items.
Physical Exam	PX-1	Form may be source for all items.
Protocol Deviation Log	PDL-1	Form may be source for all items.
Ring Adherence	RA-1	Form may be source for all items.
Ring Collection and Insertion	RCI-1	Form may be source for all items except item 3. Pharmacy dispensing records should be source for item 3.
Specimen Storage	SS-1	Form may be source for all items (or lab requisition).
Termination	TM-1	Form may be source for all items.
Vaginal Practices	VP-1	Form may be source for items 1, 2 and 2b. Items 2a and 2a1 should be completed based on source data recorded on source documents.

Section Appendix 2-3
CRFs Not Used as Source Documents

CRF Name	CRF Acronym	Comments
End of Study Inventory	ESI-1	All items should be completed based on source data recorded on source documents.
Safety Laboratory Results	SLR-1	All laboratory value items should be completed based on laboratory source documents. Form may be source for non-laboratory value items.
STI Test Results	STI-1	This form or laboratory testing logs may be source for items 1-2. Items 3-4 should be completed based on laboratory source documents.
Pre-existing Conditions	PRE-1	All items should be completed based on source data recorded on source documents.
Follow-up Visit Summary	FVS-1	All items should be completed based on source data recorded on source documents.
HIV Confirmatory Results	HCR-1	All items should be completed based on source data recorded on source documents.
HIV Results	HIV-1	All items should be completed based on source data recorded on source documents.