Standard Operating Procedures

Chain of Custody for Paper Forms Plan for the Botswana HIV Case Based Surveillance Protocol

Republic of Botswana

MINISTRY OF HEALTH & WELLNESS

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Date of Development: July 2021
Updated: October 2021

1.0 TITLE

Chain of Custody for paper Case Report Forms (CRF)

2.0 PURPOSE

2.1 To define procedures which CBS staff will follow for the handling, transportation, handover, and storage of completed HIV CRFs.

3.0 RESPONSIBLE PARTIES

3.1 All District TOTs are responsible for ensuring that all staff are knowledgeable about the contents of these SOPs.

3.2 All staff are responsible for adhering to these SOPs.

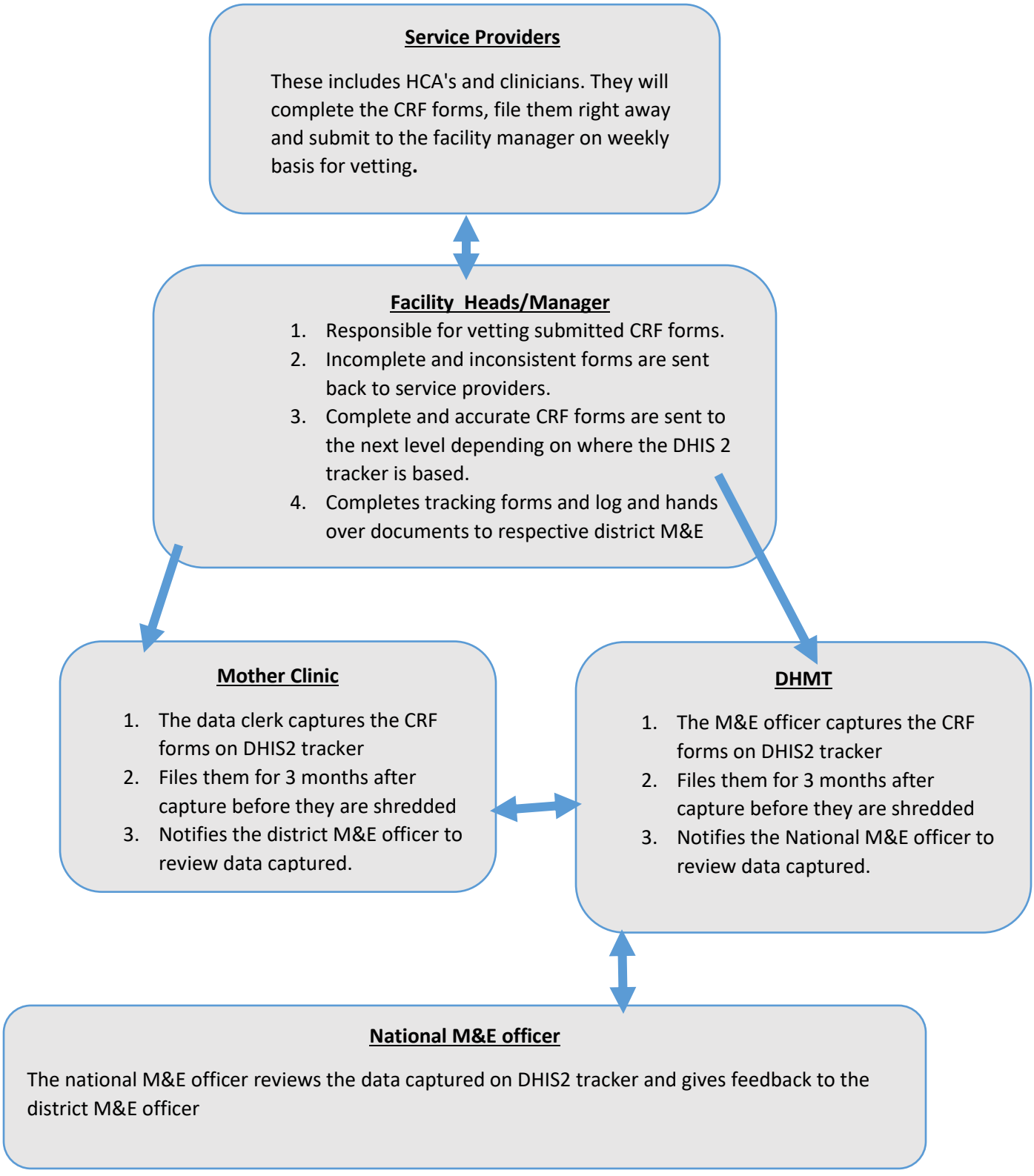
4.0 INVENTORY OF PAPER FORMS

4.1 The complete inventory of paper forms completed by the CBS facility staff is attached as an appendix to this SOP.

5.0 PROCESS

Different members of the CBS team are responsible for steps along the chain of custody of the paper CRFs as described in the various SOPs and in alignment with the CBS Protocol.

Figure 1: Flow of Paper CRFs from Health Facility to Mother Facility/District



6.0 CHAIN OF CUSTODY OF PAPER CRFs FROM THE CENTRAL OFFICE TO THE Health Facility:

6.1 CRFs are to be printed by the Ministry of Health and Wellness (MOHW) Surveillance Office in accordance with the CBS Printing Master List which is attached to as an appendix to this SOP. The printed CRFs are distributed through the District ToTs to facilities that do not have electronic medical records (EMRs) and will be using paper forms for data collection.

6.2 At district level, the printed paper forms are distributed to the facilities in quantities pre-determined by the district TOTs in the Printing Master list.

7.0 Chain of Custody of Paper Forms from the Field:

7.1 CBS CRFs:

Completed CBS CRFs are stored in a lockable cabinet at the end of each workday. The facility lead conducts quality assurance (QA) on the forms to ensure that information was correctly captured. Any errors detected are to be corrected by the facility concerned according to Good Clinical Practice (GCP) guidelines. Any forms with errors MUST be corrected before they are transferred to the next individual, or they will be returned and delay the process.

The facility lead also ensures that the number of forms with their unique identifiers (PTIDs and Names) in their custody corresponds with the number and unique IDs. The facility leads files the signed forms and stores them in a lockable cabinet which is in a lockable room.

At the end of every week, the facility lead transfers the completed forms to the designated facility at which DHIS-2 is housed for data capture.

7.2 Incident Report Form

Incident Report Forms are completed by any member of the team in accordance with the SOPs on Incident Management. Completed incident report forms should be reported in line with the SOPs on incident management. The steps subsequently outlined in this section of the SOP describe the chain of custody of the completed paper documents.

7.2.1 Incident Report Forms Completed at facility/lab:

If the incident report form is completed by a facility member, the personnel who completes the form submits the paper document to the facility/lab lead. The facility/lab lead files the completed forms and stores them in a lockable cabinet. Every week, these documents are to be submitted by the facility/lab lead to the District ToT for filing. The district ToT is responsible for sending the completed incident report forms to the Surveillance Officer for storage in locked cabinets on a regular basis.

7.2.2 Incident Report Forms Completed in the district

If the incident report form is completed by a member of the district team, the member who completes the form submits the paper document to the District ToT for filing. The district ToT is responsible for sending the completed incident report forms to the Surveillance Officer for storage in locked cabinets on a weekly basis.

7.2.3 Incident Report Forms Completed in the Central Office

If the incident report form is completed by a member of the MOHW central office team, the team member who completes the form submits the paper document to directly to the Surveillance Officer.

The Surveillance Officer conducts a reconciliation process to ensure that all expected forms (based on the incident tracking log) have been received. At the central office, the Surveillance Officer stores the completed incident report forms in locked cabinets in folders for each region. Each regional folder is arranged by district in accordance guidelines described in the SOP on Regulatory Management. Only the Surveillance Officer and their designate will have access to these folders. All stored paper documents are archived for a maximum of five years after all protocol testing has been completed.

7.3 Monitoring and Supervision Checklists:

Monitoring checklists are used by all TWG members across different levels during monitoring visits in accordance with the CBS Monitoring Plan. Completed checklists are collected by the head of the monitoring team and submitted to the Surveillance Officer end of the monitoring visits. At the central MOHW office, the Surveillance Officer stores the completed forms in locked cabinets in folders for each

district. Only the CBS TWG have access to these folders. All stored paper documents are archived for a maximum of five years after all protocol testing has been completed.

Appendix 1: CBS Paper Based Forms Tracking Form

District: _____ Facility: _____

Date (dd/mm/yyyy): _____ Form Name:_____

Serial No	District/facility/First Name

_____

Facility LEAD- INITIALS, SIGNATURE and DATE (dd/mm/yyyy)

_____

DISTRICT OFFICER- INITIALS, SIGNATURE and DATE (dd/mm/yyyy)

_____

SURVEILLANCE OFFICER- INITIALS, SIGNATURE and DATE (dd/mm/yyyy)

Appendix 2: CSB Chain of Custody Tracking log

Date of Transfer	Name of person handing over documents	Designation	District	Location of hand over	Number of forms handed over	Name of forms (codify)	Signature	Name of recipient receiving document/ form	Designation	District	Confirm # of forms/docs handed over	Date of Receipt	Signature of recipient

Appendix 3: Incident Report Form

Incident Report Form

District: _____ Date: _____

Report Initiated By (name and ID): _____

Facility of report: _____

1. Description of Incident (Summary of incident):
Use the spaces below to describe the incident, the immediate action taken in response to the event, the survey phase in which the event occurred, and the category that ***best*** describes the event.

Briefly describe the incident:

_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____
_____

Briefly describe the immediate action:

Incident reported to the following people/organizations:

_____
_____
_____
_____
_____

2. Incident Cause and Corrective/Preventive Actions:
Use the spaces below to describe the cause of the event, identify actions needed to avoid the event in the future, and identify the impact of the event.

Briefly describe the cause of the event (use root cause analysis tools, if possible):

Briefly describe the corrective actions to be implemented:

Activity	When	Person Responsible

3. Supervisor Review and Incident Referral

The supervisor of the individual that initiated the report is required to review the report, verify that the appropriate corrective actions have been enacted (if necessary) and, if the incident occurred in a different location or survey phase, refer the report to the appropriate supervisor (Referee Supervisor) at that location or survey phase.

Supervisor Signature: _____

Name of supervisor: _____

Upon completion, a copy of the Incident form should be kept on file in the Central office

Appendix 4: CRF for newly diagnosed PLHIV_BW

Botswana Ministry of Health and Wellness
Case Report Form for Newly Diagnosed Persons Living with HIV infection

This form may be completed by a health care provider on the day of HIV diagnosis or within 7 days.
Please record all date as dd/mm/yyyy

Section A: Client Unique Identifier *(Personal identifying information from this section will not be included in the surveillance database)*

1. **Name:** First_____ Surname _____ Middle _____
2. **Alternative name:** _____ Not available ☐
3. **Place of birth:** City/town/village_____ province/state/district _____ Country/code _____
4. **DOB** : / /
5. **National identification** (check all that apply):
   National ID (OMANG) : _____ Birth certificate number: _____
   Driver licence : _____ Passport number : _____ Not available ☐
6. **HIV care/ART ID number:** _____ Not available ☐
7. **Index case number**: _____ Not available ☐

Section B : Client Demographic Information

1. **Marital status:** Never married/single ☐ Married-monogamous ☐ Co-habiting ☐ Married-polygamous ☐ Divorced/separated ☐ Widow/Widower ☐
2. **Location and type of residence:**
   District name: _____ Village/ward/kgotla:_____
   Residence (check one only): House/apartment/flat ☐ Prison ☐
   Temporary house ☐ Homeless ☐ Shelter ☐
3. **Age**: year(s) month(s)
4. **Sex at birth:** Male ☐ Female ☐

Section C: Facility information

1. **District:** _____ **2. Testing Site Name/Code:** _____
5. **Reporting Site/Code:** _____
6. **Point of HIV testing service where the case was diagnosed:**
   HTS ☐ ANC ☐ Maternity ☐ IDCC ☐ TB ☐ VMMC ☐
   A&E ☐ Inpatient Ward ☐ STI ☐ OPD ☐ Child Welfare ☐
   Other ☐, specify: _____

Section D: Report reception/Data management information

1. Date Form Completed: / /
2. Date Report Received: / /
3. Date Report Entered: / /

Section E: Index Testing

1. **Contact of index case?** Yes ☐ Index case ID number _____ Not available ☐
   Index case ART ID number _____ Not available ☐
   No ☐ Refuse ☐

(If client aged < 5 years and identified through PMTCT: HTS and ART ID number of the biological mother should be used)

Section F: HIV Testing

1. **Date of first HIV positive test (dd/mm/yyyy):** / / **Type of HIV test:** ☐ Rapid Test ☐ PCR (EID testing)
2. **Date of HIV positive verification test (dd/mm/yyyy):** / /

Client Clinical History Information (client aged ≤ 5 years)

1. **Birth weight:** ____kg **Gestation at birth:** ____ weeks
2. **Maternal ART:** Yes ☐ No ☐ Don't know ☐
   If yes, ART initiation: Before pregnancy ☐ During pregnancy ☐ During birth ☐
   After giving birth ☐ Don't know ☐
   ART regimens taken before or during pregnancy or during or after giving birth (list all): _____
3. **Infant ARV prophylaxis:** Yes ☐ No ☐ Don't know ☐
   If yes, NVP ☐ NVP & AZT ☐ Other ☐ specify:_____ Duration:____weeks
4. **Birth defects (ICD-10):** Yes ☐ No ☐ Don't know ☐
   If yes, specify_____

Section H: Client Clinical History Information (client aged > 5 years)

1. **Date of most recent HIV-negative test**: / / or months ago Never been tested ☐
2. **Ever been on PREP** Yes ☐ No ☐ Refuse ☐ Unknown ☐
3. **Ever been on ART** Yes ☐ No ☐ Refuse ☐ Unknown ☐
4. **Ever received ARV/ART prophylaxis to prevent mother to child HIV transmission?**
   Yes ☐ No ☐ Refuse ☐ Unknown ☐
5. **If the client is a girl/woman ≥12 years of age**: a. Pregnant ☐, *Gestation (weeks)*:
   b. Breastfeeding ☐, Post-delivery (months): (Up to 24 months)
   c. Not pregnant or breastfeeding ☐

Section I: Client Clinical Information at the time of HIV Diagnosis

1. Was the WHO clinical stage assessed?
No ☐ Yes ☐ → date: / /
Result: Stage I ☐
Stage II ☐
Stage III ☐
Stage IV ☐

2. 1st CD4: Not done: ☐
Sample collection date: / /
Sample test date: / /
Result count:
Result percent:

3. ART initiation
No ☐ → Referral ☐ Refused ☐
Yes ☐ Initiation date: / /
Regimen: _____

4. Was cryptococcal infection diagnosed?
No ☐ Not done ☐
Yes ☐ à date / /
Results: CrAg positive ☐
CM/disseminated ☐

6. Were any other opportunistic infections diagnosed?
No ☐
Yes ☐ à date / /
If yes, specify _____

5. Was Tuberculosis diagnosed?
No: ☐ → Was TB preventive therapy (TPT) given?
Yes ☐ → date: / /
Regimen: _____
(e.g., INH, 3HP)
No ☐ → Reason: ☐ Client refused
☐ Contraindication
☐ Already completed TPT
☐ No drug supplies

Yes: ☐ à date / /
Symptom screening positive ☐
Sputum positive ☐ Xray positive ☐
Other test positive ☐, specify _____
Was the patient on TB treatment?
Yes ☐ → Start date: / /
Regimen: _____
No ☐ → Why? _____

Not done: ☐

Appendix 5: CRF for Sentinel Events

Botswana Ministry of Health and Wellness
Case Report Form for Sentinel Events for a Previously Reported Case

This form may be completed by a health care provider every 3 months (or 6 months) from the date of HIV diagnosis per country guidelines. Please record all date as dd/mm/yyyy

Section A: Client Unique Identifier/Client Profile (*Personal identifying information from this section will not be included in the surveillance data repository)*

8. Name: First_____ Surname _____ Middle _____
9. Alternative name: _____ Not available ☐
10. Place of birth: City/town/village_____ province/state/district _____ Country/code _____
11. DOB: / / **Age**: year(s) month (s)
12. Sex at birth: Male ☐ Female ☐
13. National identification (check all that apply):
National ID (Omang): _____ Birth certificate number: _____
Driver's license: _____ Passport number: _____ Not available ☐
14. HIV care/ART ID number: _____ Not available ☐

SECTION B: Care and Treatment Facility Information

2. District: _____
3. Village/city: _____
4. Care and Treatment Facility Name/Code: _____

SECTION C: Report Reception/Data Management Information

4. **District:** _____
5. **Reporting facility/Code:** _____
6. **Date Form Completed:** / /
7. **Date Report Received:** / /
8. **Date Report Entered:** / /

Section D : Client Latest Demographic Information

1. Location and Type of Resident
a. District name: _____
b. Village/ward/kgotla:_____

2. Marital Status
Never married/single ☐ Married-monogamous ☐
Co-habiting ☐ Married-polygamous ☐
Divorced/separated ☐ Widow/Widower ☐

Section D: Client Testing and Treatment History

1. **Date of HIV diagnosis:** / / **Testing site name/code:** _____
2. **Date first enrolled in care/treatment:** / / **Care/treatment clinic name/code:** _____

3. Transferred in:
No ☐, skip to Section E
Unknown ☐, skip to Section E
Yes ☐, →Question 4

4. Transfer in date: / /
5. Previous facility name/code: _____
6. Patient was on ART: No ☐ Unknown ☐
Yes ☐, HIV Care/Treatment ID number _____
7. Date of ART initiation in previous facility: / / Unknown ☐
8. Regimen _____ Unknown ☐

Section E: Antiretroviral Treatment (ART) during the reporting period

Current **HIV Care/Treatment ID number:** _____ (Note: a patient could receive more than one regimen)

On 1st line: ☐ Date started on 1st line / / Regimen: _____
2nd line: ☐ Date started on 2nd line / / Regimen: _____
3rd line: ☐ Date started on 3rd line / / Regimen: _____
On a special (prescribed by a doctor) regimen (not 1st or 2nd or 3rd line):
No ☐ Yes ☐ → Date started on the special regimen: / / Regimen: _____

Reasons to switch a new ART regimen:

Treatment failure (Viral load not suppressed or drug resistance) ☐ Adverse drug reaction ☐ Gastrointestinal ☐
Skin ☐ CNS ☐ Haematological ☐ Hepatic dysfunction ☐ Metabolic ☐ Headache ☐
Kidney dysfunction ☐ Bone dysfunction ☐ Fatigue ☐ Treatment guideline change ☐
ARV shortage/stockout ☐ Drug-drug interactions ☐ Pregnancy/planning to become pregnant ☐
Other ☐, Specify: _____

Section F: Women and Child Health during the reporting period (for female patient only)

1. Was she pregnant?
   - Yes ☐ →
   - No ☐, skip to G
   - Don't know ☐, skip to G

a. Last day of menstrual period / / Don't know ☐
b. Due date / / Don't know ☐
c. Attend antenatal care? No ☐ Don't know ☐
Yes ☐ → Date of 1st ANC visit: / / Gestation (weeks): ____

2. Did she give birth?
   - Yes ☐, →
   - No:
     Miscarriage ☐, skip to G
     Stillbirth ☐, skip to G
     Abortion ☐, skip to G
     Don't know ☐, skip to G

The child's date of birth: / / Don't know ☐
Gestation at delivery: ___ weeks **Birth weight:** ___ kg
Birth defects (ICD-10)**:** Yes ☐ No ☐ Don't know ☐
If yes, Specify_____
Was the baby diagnosed with HIV?
- No ☐ Don't know ☐
- Yes ☐ → Date of the diagnosis / / Not available ☐
  Was the child initiated on ART? No ☐ Yes ☐
  ART ID number? _____ _ Not available ☐

Section G: Laboratory Test Information

CD4 T cell count and percentage during the reporting period

Date of sample collection: / / CD4 count _____ cells/µL CD4 percentage _____%

Date of sample collection: / / CD4 count _____ cells/µL CD4 percentage _____%

HIV viral load RNA test during the reporting period

Date of sample collection: / / Detectable copies _____ copies/mL
Detectable copies _____ log Undetectable ☐

Date of sample collection: / / Detectable copies _____ copies/mL
Detectable copies _____ log Undetectable ☐

HIV Drug Resistance during the reporting period

Date of sample collection: / / Date of sample tested: / / Sample rejected ☐ Not done ☐

Major mutation results: NRTI ☐ NNRTI ☐ PI ☐ INI ☐ Other ARV class ☐, specify ART name_____

Section H: Clinical Information During the Reporting Period

Was Tuberculosis diagnosed?
No ☐ Not done ☐
Yes ☐ à date / /
Symptom screening positive ☐
Sputum positive ☐
Xray positive ☐
Other positive ☐,
specify _____

Was the patient on TB treatment?
Yes ☐ à Start date: / /
Regimen:
_____
No ☐ à Why? _____

Was TB preventive treatment (TPT) completed?
No ☐ à Why? Non-adherence ☐
Developed active TB ☐
No drug supply ☐
Adverse drug reaction ☐,
specify _____
(e.g., rash, neuropathy, liver toxicity)
Yes ☐ à Start date: / /
End date: / /
Regimen: _____
(e.g., INH, 3HP)

Was the patient LTFU?
No ☐
Yes ☐ à date / /

Was the patient transferred out?
No ☐
Yes ☐ àdate / /

Did the patient die?
No ☐
Yes ☐ à date / /
Cause of death:
_____

Was cryptococcal infection diagnosed?
No ☐ Not done ☐ Yes ☐ à date / /
Results: CrAg positive ☐ CM/disseminated ☐

Was the WHO clinical stage assessed?
No ☐ Yes ☐ → date: / /

Was the patient on treatment? No ☐ à Why? _____ Yes ☐ à Start date: / / Regimen: _____	Result: Stage I ☐ Stage II ☐ Stage III ☐ Stage IV ☐
Were any other opportunistic infections diagnosed? No ☐ Yes ☐ à date / / Specify:_____	

INI: integrase Inhibitors/Dolutegravir