

Instructions for Follow-up in the EuroSIDA Study

Dataset 54, Autumn 2026

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Instructions for Follow-Up in the EuroSIDA Study

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Please study these instructions, and the list of definitions for the various diseases before you start entering data into the REDCap forms.

General information

The EuroSIDA follow-up in REDCap consists of the following forms:

- **EuroSIDA Follow-up form (FU54 Autumn 2026)**
- **Cause of Death (CoDe) event form**
- **RESPOND Event Form**
- **EuroSIDA Event Form for use of long-acting cabotegravir + rilpivirine**

Access to REDCap forms

Detailed instructions for REDCap can be found below.

Historically reported data has been pre-uploaded to the EuroSIDA follow-up form. Kindly make sure that you complete all forms for all uploaded participant forms.

All principal investigators should have received a username and a password for REDCap by email. Contact the coordinating centre if you or anyone from your team need access to REDCap or have questions regarding the REDCap forms.

Unresolved queries of missing event forms may be listed and attached. Resolve all requested information and return the list to the coordinating centre by e-mail.

For sites that report data in an Electronic Access database

Sites submitting data electronically should use the RESPOND Electronic Submission Tool (REST), a web-based submission tool available through the CHIP website. REST allows sites to submit data using the predesigned Access template and to check data quality and completeness before submission. The tool generates a report of errors, and data is only submitted after a final submission step, allowing sites to identify and correct errors beforehand. A REST guide will be sent to all participating sites. Sites submitting data through REST are kindly asked to also complete the following forms in REDCap:

- **RESPOND Event Form**
- **Cause of Death (CoDe) form**
- **EuroSIDA Event Form for use of long-acting cabotegravir + rilpivirine**

Unknown dates

Unknown dates for previously reported data are reported as “dummy dates”. See the instructions for reporting unknown dates at the top of each section in REDCap, or in the SOP for electronic data transfer.

Below detection limit

Indicate measurements below detection limit (DL) as “-1”.

Case definitions

Find the “**List of Definitions on Clinical Events**” for AIDS-defining diagnoses (except malignancies) enclosed in this document or find it on the EuroSIDA website. The updated Manual of Operations of Clinical Events can be found on the EuroSIDA website as well: <https://www.chip.dk/Studies/EuroSIDA/Study-documents>.

The EuroSIDA Follow-up form (FU 54 Autumn 2026)

Please complete all requested information for all patients.

Present visit

Enter the date of the present visit in **Section A** (i.e., the data of the patient’s most recent clinic visit). If the patient has not been seen since last reported visit, please provide the reason. You may then leave the remaining sections blank and continue straight to the final “Status” section. If the patient has died, complete the Cause of Death (CoDe) event form. If the patient has been seen since last follow-up, ensure that all sections of the follow-up form are completed.

Events

See the “**List of Definitions on Clinical Events**” for the relevant events collected in **EuroSIDA FU54**. If a new event has occurred since the last follow-up, report the event and the ‘date of event’ in the follow-up form. If the patient has experienced a bone fracture or been diagnosed with AIDS or non-AIDS defining cancer, end stage liver disease (including liver transplantation), end stage renal disease (including renal transplantation), myocardial infarction, invasive cardiovascular procedure, or a stroke since the last follow-up (DS53), follow the link in the follow-up form to complete the RESPOND Event Form.

The ‘Status’ section must be completed for *all* patients when all available data has been entered. By completing this form, you indicate that all available data has been entered and that the follow-up form is complete.

Cause of Death (CoDe) event form

Provide the ‘**date of death**’ and a brief narrative of the sequence of events leading to death. Provide a summary of the causal relation between the conditions leading to death and upload any relevant source documentation (e.g. admission letter for the admission related to death, a discharge letter, an autopsy report or the like).

RESPOND Event Form

Complete the event form for patients who have experienced one or more of the following events:

- Bone fracture
- Cancer, AIDS and Non-AIDS defining
- End stage liver disease or liver transplantation (ESLD)
- End stage renal disease or kidney transplantation (ESRD)

- Invasive cardiovascular procedure (ICP)
- Myocardial infarction (MI)
- Stroke

Note: The date of the event should still be indicated in the Follow-up form, but further details are collected in the separate REDCap RESPOND event form.

EuroSIDA Event Form for use of long-acting cabotegravir + rilpivirine

This form should be completed for participants who have started **long-acting injectable Cabotegravir + Rilpivirine (CAB+RPV LAI)**. The form is open-ended and should be updated annually with all injections since last follow-up, each year.

From FU54, the event form and injection forms in project “*EuroSIDA Event form for use of long-acting cabotegravir+ rilpivirine*” should be completed for new EuroSIDA participants who have started CAB+RPV LAI treatment with first injection **after 1 January 2026**.

For the existing CAB+RPV LAI participants in the project, the injection forms should be up to date if their first injection was between **1 January 2021 and 31 December 2025**.

All CAB+RPV LAI participants, both new and existing, should be followed prospectively until the earliest of death, loss to follow-up, withdrawal of consent, or 31 December 2030. Participants who discontinue CAB+RPV LAI for any reason will continue to be followed on annual clinical follow-up forms, allowing review of virological outcomes for up to 48 months after discontinuation or until 31 December 2030, whichever occurs first.

REDCap instructions for Follow-Up in the EuroSIDA Study

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ACCESS TO REDCap

Enter the address: <https://chip-crf.info/redcap/> into your browser and log in with your username and password. If you have lost your username/password, or if you have not received one yet, contact the Coordinating Centre at eurosidea.rigshospitalet@regionh.dk.

The first time you log in, you will be asked to change the password and set up a password recovery question. Note that your access is personal, and if more staff at your site need access, contact the Coordinating Centre.

FIND YOUR PROJECT

Go to **My Projects** tab and find the list of all the forms.

EuroSIDA Follow-up (FU 54 Autumn 2026): Follow-up forms for all your patients should be completed in REDCap. The follow-up form contains several sections, which should all be reviewed and/or completed unless there is no new data since last follow-up. If there is no new information since the last follow-up, indicate the reason in section A, and then complete the section and the final status form.

Note: All '*Must Provide Values*' must be completed (marked in the FU form with **must provide value*), unless the patient is dead, lost to follow-up or has not been seen since the last follow-up, indicated in Section A. If there are no new values to enter in a given field, you should mark this with '**No**', instead of leaving the field blank. **Reimbursement will be based on the completeness of 'Must Provide Values'.**

FIND A PATIENT'S FOLLOW-UP FORM/PATIENT RECORD

The EuroSIDA Follow-up form (FU54 Autumn 2026) has preloaded patient records with the historical information you have previously recorded in enrolment and/or previous follow-up forms. Preloaded data is listed in grey fields. To find a patient record:

1. Click on the project EuroSIDA Follow-up (FU54 Autumn 2026). Click on the **Record Status Dashboard** on the left-hand side under Data Collection:

Record Status Dashboard (all records)

Displayed below is a table listing all existing records/responses and their status for every data collection instrument (and if longitudinal, for every event). You may click any of the colored buttons in the table to open a new tab/window in your browser to view that record on that particular data collection instrument. Please note that if your form-level user privileges are restricted for certain data collection instruments, you will only be able to view those instruments, and if you belong to a Data Access Group, you will only be able to view records that belong to your group.

Legend for status icons:

- Incomplete ○ Incomplete (no data saved) ○ Unverified ● Complete

Dashboard displayed: [Default dashboard] ▼ + Create custom dashboard

Displaying Data Access Group 104987 ▼

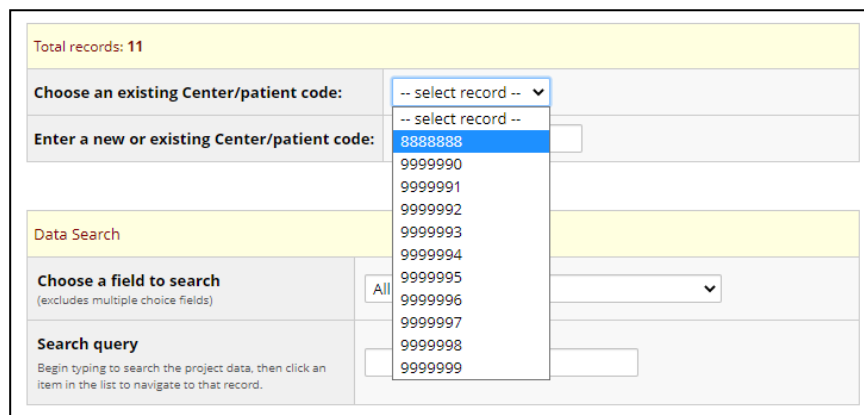
Displaying record Page 1 of 1: "9871201" through "9871512" ▼ of **26** records 100 ▼ records per page

+ Create

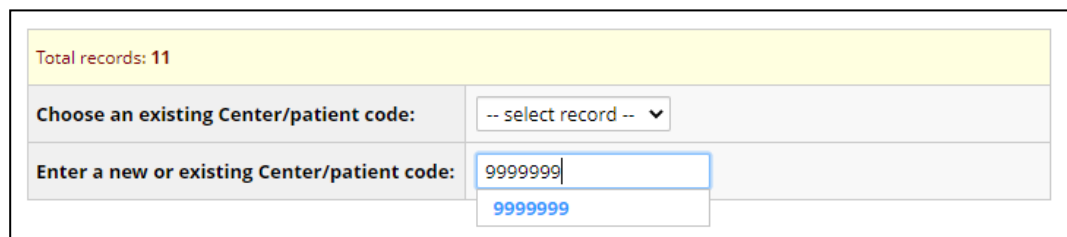
Displaying: [Instrument status only](#) | [Lock status only](#) | [All status types](#)

Center/patient code:	Section A - Demography And Basic Clinical Information	Section B1 - Laboratory Values	Section B2 - CD4, CD8 And HIV-RNA	Section B3 - Hepatitis virology, fibrosis and HCC screening	Section B5 - Plasma samples, resistance and screening for adverse effects of ART	Section C1 - Antiretroviral Treatment In The Last 5 Years	Section C2 - Risk of Cardiovascular Disease, Diabetes, Obesity and Opioid Maintenance Therapy	Section C3 - Treatment Against Hepatitis C	Section C4 - Tuberculosis	Section C5 - Treatment with anti-osteoporotic drugs and corticosteroids	Section D - Severe Opportunistic Infections and Sexually Transmitted Infections	Section E - Events	Section F - Status
	●	●	●	●	○	●	○	○	○	○	○	○	○
	●	●	●	●	●	●	○	○	○	○	○	○	○
	●	●	●	●	●	●	●	○	○	○	○	○	○
	●	●	●	●	○	●	●	○	○	○	○	○	○
	●	●	●	●	●	●	●	○	○	○	○	○	○
	●	●	●	●	○	●	●	○	○	○	○	○	○
	●	●	●	●	●	●	●	○	○	○	○	○	○
	●	●	●	●	○	●	●	○	○	○	○	○	○
	●	●	●	●	○	●	●	○	○	○	○	○	○
	●	●	●	●	○	●	●	○	○	○	○	○	○
	●	●	●	●	○	●	●	○	○	○	○	○	○
	●	●	●	●	○	●	●	○	○	○	○	○	○
	●	●	●	●	○	●	●	○	○	○	○	○	○
	●	●	●	●	○	●	●	○	○	○	○	○	○
	●	●	●	●	○	●	●	○	○	○	○	○	○
	●	●	●	●	○	●	●	○	○	○	○	○	○
	●	●	●	●	○	●	●						

Find the record using the **Choose an existing Center/patient code** drop down box:

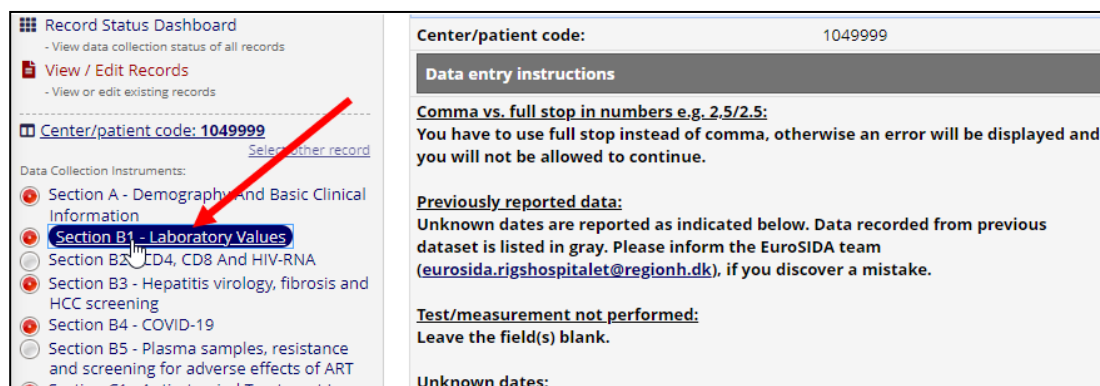


Or by entering the PID in **Enter a new or existing Center/patient code:**



ENTER DATA INTO THE PATIENT FOLLOW-UP FORM/PATIENT RECORD

1. The EuroSIDA Follow-up (FU54 Autumn 2026) contains a form for each section. You can navigate between the different sections using the links on the left-hand side:



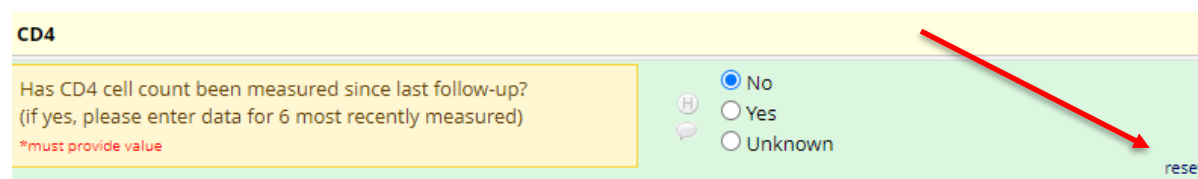
The colored icon in front of the form denotes the status, i.e.:

- **Green** (complete): The form/section is complete.
- **Yellow** (unverified): The form/section has been edited but is incomplete.
- **Red** (incomplete): The form/section contains preloaded data and has not been reviewed and/or the form/section has been saved, but data is incomplete and will be completed/reviewed later.

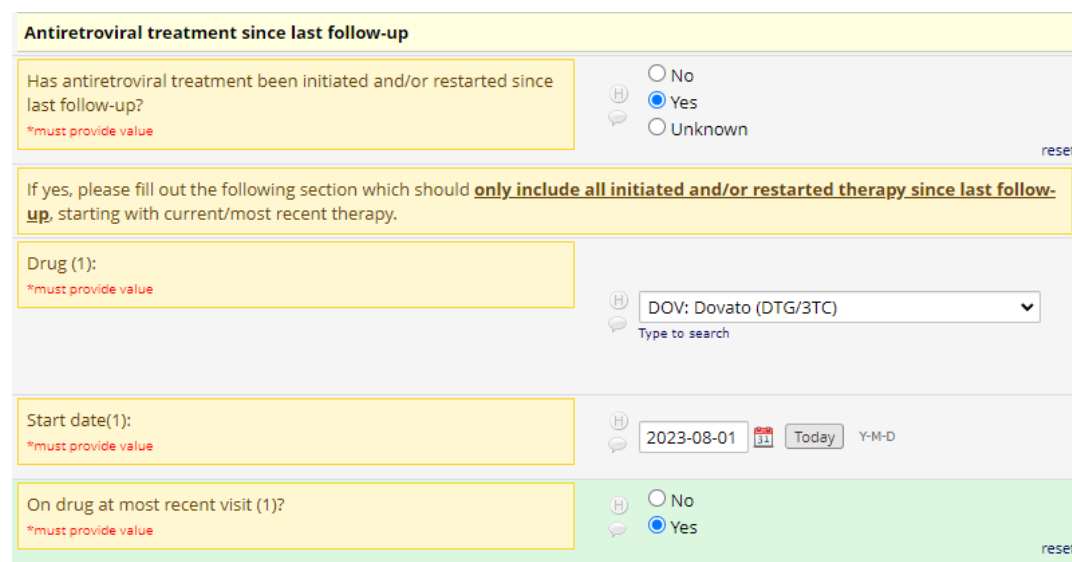
- **Grey** (incomplete): No data has been entered/saved.

2. Fill out the forms/sections. Data should be entered into the **yellow fields**. Previously reported data is displayed in **grey fields**. **You cannot edit previously reported data. If you find an error, send an email describing the PID, section and the correction.** In some sections, e.g., section C1, the yellow fields are located amongst the grey field's historical data.

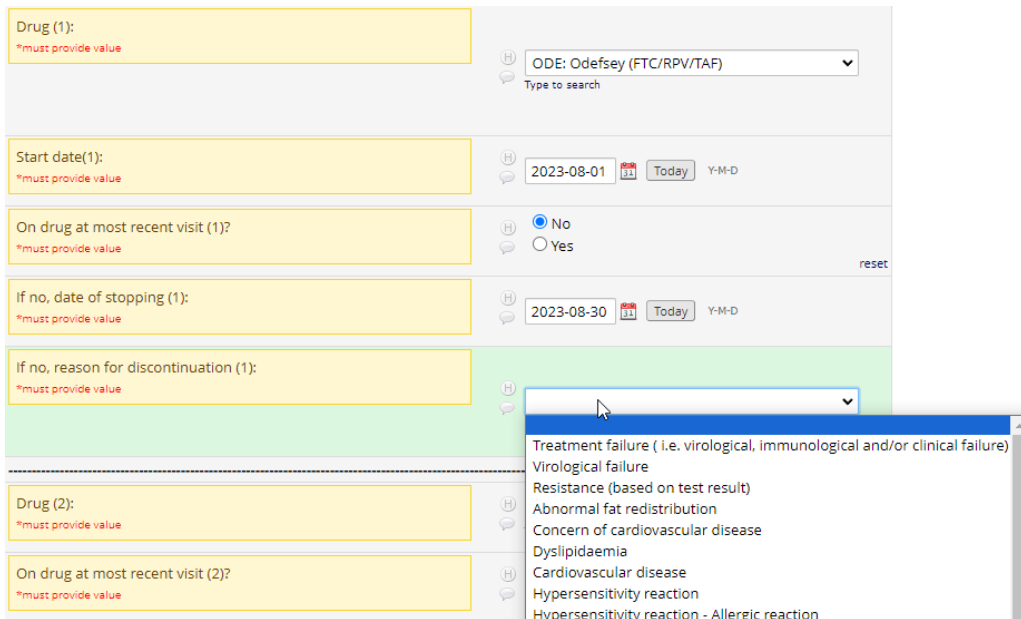
To remove an answer, click **Reset**.



This screenshot shows you how to report that the patient has started a new antiretroviral treatment:

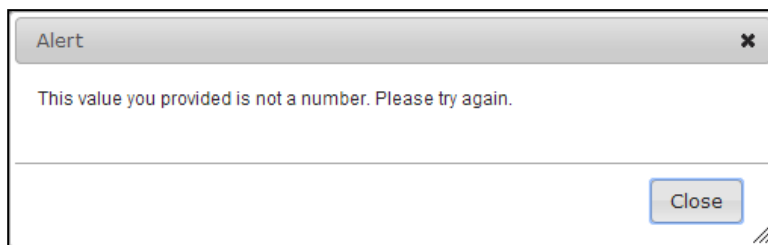


This screenshot shows you how to report that the patient has stopped antiretroviral therapy, which they were receiving at the last visit. Indicate the date and the reason for discontinuation:



Comma vs. full stop

Use full stop instead of a comma. Otherwise, you will receive this error:

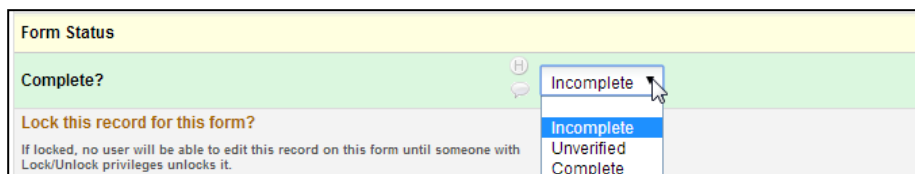


3. Select status at the bottom of the form/section.

Incomplete: The form/section contains incomplete data and will be completed later.

Unverified: The form/section contains incomplete data and will be completed later. Use this status if you are interrupted and need to come back to it later.

Complete: The form status/section contains all available data.

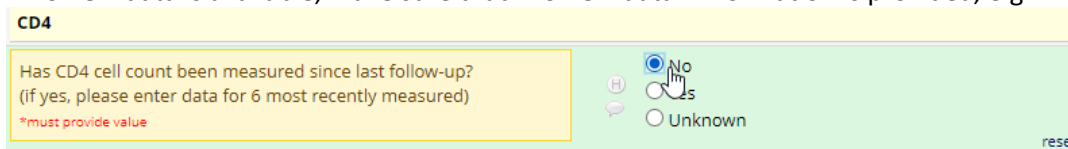


4. Click Save & Exit Form, Save & Stay or Save and go to Next Form.

FINALIZE EACH PATIENT RECORD

Before finalizing a patient record, make sure that you have:

- Entered all data available for the patient.
- If no new data is available, make sure that “no new data” information is provided, e.g.:



- If the patient has died and no new data is available *or* if the patient has not been seen since last follow-up, indicate this in Section A of the Follow-up form and complete the final Status Section.
- Completed all sections in all applicable forms.

Click “Status” in the left side menu and confirm that you have finalized your data collection by choosing “Complete” in the dropdown menu. By changing the status of this form to **“Complete”**, you confirm that there is no more available data for the patient during the current follow-up period.

SAVE OR PRINT RECORD FOR YOUR USE

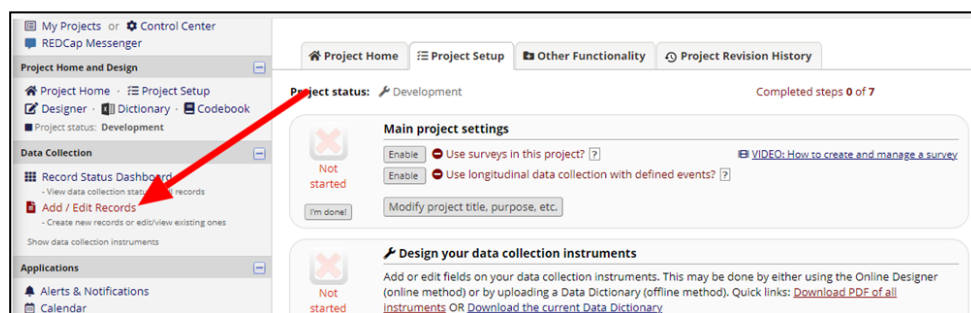
If you wish to download your reported data from REDCap, contact the coordinating center detailing which forms or data you wish to download.

ADD NEW PATIENT RECORD

The RESPOND Event form, the CoDe form and the Cabotegravir+Rilpivirine form do not have preloaded patient record data – a new record needs to be added manually.

To add a new record:

- Click on one of the projects (i.e., RESPOND Event form or CoDe form). Click **Add/Edit Records** on the left-hand side under ‘Record Status Dashboard’:



- Type the EuroSIDA Patient Identification code [center code (3 digits) followed by patient code (4 digits) e.g., 1502001] and press **ENTER**:

Total records: 11	
Choose an existing Center/patient code:	-- select record -- ▾
Enter a new or existing Center/patient code:	9999999

4. Click on the circle under event 1 (only relevant for the Respond Event form):

NEW Patient ID: 9999991

Data Collection Instrument	Event 1	Event 2	Event 3	Event 4	Event 5
Respond Event Form	☒	☐	☐	☐	☐

Choose **Event 1** by clicking here.

List of Definitions for Clinical Events for the EuroSIDA Study

Dataset 54, Autumn 2026

LIST OF DEFINITIONS

The list below is definitions for the AIDS-defining events collected in EuroSIDA. The diagnostic criteria and duration required for classifying as a “definitive” or a “presumptive” event are indicated (for opportunistic infections only). For the definitions of clinical events where completion of a RESPOND Event Form is indicated, see the **Manual of Operations (MOOP) for clinical events** in RESPOND and EuroSIDA.

Section D: Severe opportunistic infections

DEM: AIDS dementia complex

Definitive:	Disabling cognitive and/or motor dysfunction, and no other causes by CSF exam and brain imaging or by autopsy
Presumptive:	Same as above, but no CSF and brain imaging performed

BCNE: Bacterial pneumonia, recurrent (≥ 2 episodes within 1 year)

Definitive:	X-ray evidence of pneumonia not present on previous X-rays <u>and</u> culture of bacteria that typically cause pneumonia (other than <i>M. Tuberculosis</i>)
Presumptive:	Acute radiological findings (new X-ray evidence not present earlier) <u>and</u> acute clinical findings

CANO: Oesophageal candidiasis

Definitive/autopsy:	Gross inspection by endoscopy/autopsy or by microscopy (histology)
Presumptive:	Recent onset retrosternal pain on swallowing and confirmed oral or pharyngeal candidiasis

CRCO: Cryptococcosis, extrapulm

Definitive/autopsy:	Microscopy, culture of, or antigen detection in affected tissue
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CRSP: Cryptosporidiosis (duration > 1 month)

Definitive/autopsy:	Microscopy. Duration of diarrhoea for more than 1 month
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CMVR: Cytomegalovirus retinitis

Presumptive:	Loss of vision and characteristic appearance on serial ophthalmoscopy, progressing over several months
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CMVO: Cytomegalovirus (pneumonia, oesophagitis, colitis, adrenalitis, other organs)

Definitive/autopsy:	Microscopy (histology or cytology)
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HERP: Herpes simplex ulcers (duration > 1 month) or pneumonia/oesophagitis

Definitive/autopsy:	Microscopy, culture of, or antigen detection in affected tissue
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HIST: Histoplasmosis (extrapulm.)

Definitive/autopsy:	Microscopy, culture of, or antigen detection in affected tissue
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WAST: HIV wasting syndrome

Definitive:	Weight loss (over 10% of baseline) <u>with no other cause</u> , and 30 days or more of either diarrhoea or weakness with fever
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ISDI: Isosporiasis diarrhoea (duration > 1 month)

Definitive/autopsy:	Microscopy (histology or cytology). Duration of diarrhoea for more than 1 month
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LEU: Progressive multifocal leukoencephalopathy (PML)

Definitive/autopsy:	Microscopy (histology or cytology)
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Presumptive: Progressive deterioration in neurological function and CT/MR scan evidence

MC: Mycobacterium MAC/Kansasii (extrapulmonary only)

Definitive: Culture

MCP: Mycobacterium tuberculosis, pulmonary

Definitive: Culture or PCR positive for Mycobacterium Tuberculosis

Presumptive: Smear positive for acid fast bacilli or a biopsy suggestive of Mycobacterium Tuberculosis by histology

MCX: Mycobacterium tuberculosis, extrapulmonary

Definitive: Culture or PCR positive for Mycobacterium Tuberculosis

Presumptive: Smear positive for acid fast bacilli or a biopsy suggestive of Mycobacterium Tuberculosis by histology

MCPO: Mycobacterium, other type (pulmonary)

Definitive: Culture (indicate type)

Presumptive: Smear positive for acid fast bacilli (species not identified by culture)

MCXO: Mycobacterium, other type (extrapulmonary)

Definitive: Culture (indicate type)

Presumptive: Smear positive for acid fast bacilli (species not identified by culture) on microscopy of normally sterile body fluid/tissue

PCP: Pneumocystis jirovecii pneumonia

Definitive: Microscopy (histology or cytology)

Presumptive: Recent onset of dyspnoea on exertion or dry cough, and diffuse bilateral infiltrates on chest X-ray and $pO_2 < 70$ mmHg and no evidence of bacterial pneumonia or viral pneumonia caused by SARS-CoV-2

SAM: Salmonella bacteraemia (non-typhoid) (≥ 2 episodes)

Definitive: Culture

TOX: Toxoplasmosis, brain

Definitive: Microscopy (histology/cytology)

Presumptive: Recent onset focal neurological abnormalities or reduced level of consciousness, and mass effect lesion on scan, and specific therapy response

Shipping Plasma Samples for the EuroSIDA Study

Please note, as of **1 August 2025**, plasma samples are longer collected as part of the EuroSIDA study protocol. All samples collected up to this date and shipped to CHIP will, of course, be reimbursed.

If you wish to send plasma samples that were collected before 1 August 2025, please visit the EuroSIDA [website](#) for information on sample shipment and storage procedures.