

Manual of operations for the EuroSIDA Event Form for use of long-acting Cabotegravir+Rilpivirine electronic case report form (eCRF)

The eCRF: EuroSIDA Event Form for use of long-acting Cabotegravir+Rilpivirine (LA CAB+RPV) has been added to your list of EuroSIDA projects in REDCap. The eCRF should be completed for all participants who start (or have already started) treatment with LA CAB+RPV regimen (first injection) after **1st of January 2026** and who have not received LA CAB+RPV as part of a clinical trial.

The eCRF should be completed on an **ongoing basis**. If the LA CAB+RPV treatment has been paused or stopped, and then later re-started, this information should also be collected.

If you do not have any new participants starting LA CAB+RPV treatment at your site, please ensure that the injection data is updated for all existing participants receiving the treatment.

eCRF completion requirements: Name and date

In all forms, the name of the person completing the form and the date of completion should be entered.

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

 Adding new Center/patient code: **1111112**.

Center/patient code:	1111112
eCRF completed by:	LP
* must provide value	
98 characters remaining	
eCRF completed date:	2026-09-24  Today Y-M-D
* must provide value	

Clinical trial participants

Patients who at any time have participated in a clinical trial of LA CAB+RPV **are not eligible** for inclusion in this study. Therefore, if you select '**Yes**' to the following question, no further data entry will be possible.

Trial history	
Has the patient ever participated in a clinical trial of long-acting cabotegravir+rilpivirine?	☐ No ☐ Yes ☐ Unknown
*must provide value	

Oral lead-in antiretroviral therapy

If oral lead-in with CAB+RPV was given, the two drugs should be entered individually.

Oral lead-in antiretroviral therapy	
Did the patient receive oral lead-in therapy?	☐ No ☒ Yes ☐ Unknown
*must provide value	reset
Drug (1):	
*must provide value	
Start date(1):	 Today Y-M-D
*must provide value	
Stop date(1):	 Today Y-M-D
*must provide value	

Oral lead-in antiretroviral therapy transition

If oral lead-in therapy was stopped because LAI therapy was started, the section for the first injection will appear. If oral lead-in therapy was stopped due to other reasons, a drop-down menu with reasons for discontinuation will show. Please select the reason that best describes why lead-in was stopped. If it was stopped due to other reasons not included in the list, please select “*Other causes, not specified above*”. A free text field will then appear.

Oral lead-in antiretroviral therapy	
Did the patient receive oral lead-in therapy? *must provide value	☐ Concern of cardiovascular disease ☐ Dyslipidaemia ☐ Cardiovascular disease ☐ Hypersensitivity reaction ☐ Hypersensitivity reaction - Allergic reaction ☐ Hypersensitivity reaction - Anaphylactic reaction ☐ Injection site reaction ☐ Injection fatigue (not related to safety) ☐ Toxicity, predominantly from abdomen/GI tract ☐ Toxicity - GI tract ☐ Toxicity - Liver ☐ Toxicity - Pancreas ☐ Toxicity, predominantly from nervous system
Drug (1): *must provide value	
Start date(1): *must provide value	
Stop date(1): *must provide value	
Was oral lead-in antiretroviral therapy stopped because the patient has initiated long-acting antiretroviral therapy? (1)	

HIV Resistance Testing Collection

Information on HIV resistance testing, if available, is collected both prior to initiation and if long-acting therapy has been discontinued due to virological failure, and again at virologic failure during the 48 months after switching regimen. The EuroSIDA secretariat will send reminders for the relevant cases.

HIV resistance testing prior to initiation of long-acting cabotegravir + rilpivirine	
Has a HIV resistance test been performed prior to initiation of long-acting cabotegravir + rilpivirine (1) *must provide value	☐ No ☒ Yes ☐ Unknown
Date of most recent resistance test prior to initiation of long-acting antiretroviral therapy (1) *must provide value	2024-09-24 Today Y-M-D
Please upload a copy of the resistance test report (1)	Upload file

Form Status

When all relevant information has been collected in each form, please change the Form Status to “**Complete**”.

Injection and Dosage documentation

If treatment with LA injectable CAB+RPV was started, please select the drugs from the drop-down menu as well as the dosage of the individual drugs and date of injection. The intended dosing schedule (monthly or every two months) at the time of each injection should be selected.

Treatment with long-acting antiretroviral therapy

-- First injection --

Which long-acting antiretroviral drugs have been initiated?
*must provide value

Long acting cabotegravir + long acting rilpivirine

Dosage long acting cabotegravir:
*must provide value

600mg

Dosage long acting rilpivirine:
*must provide value

900mg

Date of first injection:
*must provide value

2026-09-24 Today Y-M-D

Intended dosing schedule of long-acting antiretroviral therapy
*must provide value

Every 2 months

Please enter all following injections in the form "Next injection". Note that each injection must be added as a new instance within the form.
If at any point a planned injection was not administered, this should also be recorded as an instance within the form.

Reporting subsequent injections

All subsequent injections will be collected on separate forms called **"Next injection"**. If at any point a planned injection was not administered, this should also be recorded in the "Next Injection" form.

Oral bridging therapy

If the patient did not receive the next planned injection, you will be asked whether oral bridging therapy was given, and if yes, please choose a reason for starting bridging therapy.

If the planned injection with long-acting therapy was not given and bridging was not started, you will be asked if the patient has later restarted long-acting antiretroviral therapy.

Has the patient received the next planned injection with long-acting antiretroviral drugs
*must provide value

☒ No
☐ Yes
☐ Unknown

If the injection was given later than 1 or 2 months +/- 7 days (depending on dosing schedule) after the previous injection, please select No.

Has the patient started bridging therapy?
*must provide value

☐ No
☒ Yes
☐ Unknown

Reason for starting bridging therapy:
*must provide value

Start date bridging therapy:
*must provide value

Stop date bridging therapy:
*must provide value

Personal decision
LAI drugs out of stock
Personal decision
Inability to come for the injection
Injection site adverse effect

Has the patient started bridging therapy? <i>*must provide value</i>	☒ No ☐ Yes ☐ Unknown	reset
Has the patient later restarted long-acting antiretroviral therapy? <i>*must provide value</i>	☐ No ☐ Yes ☐ Unknown	reset

If a decision to discontinue LA therapy has been made, please select **"No"** and the reason for discontinuation. If a decision on whether or not to restart long-acting therapy has not been made, please select "Unknown" (this should later be changed to No or Yes, in case therapy is stopped or restarted, respectively).

Has the patient later restarted long-acting antiretroviral therapy? <i>*must provide value</i>	☒ No ☐ Yes ☐ Unknown	reset
Reasons for discontinuation: <i>*must provide value</i>		

If you have any questions regarding the completion of the form, please contact eurosida.rigshospitalet@regionh.dk