

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


The eCRF for 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 at any time including participants who have received LA CAB+RPV in clinical trials.

The eCRF should be completed once annually. If CAB+RPV has been paused or stopped, and then later re-started, this information should also be collected.

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 or rilpivirine

+ Adding new Center/patient code: 1111111	
Center/patient code:	1111111
eCRF completed by:	<input type="text"/>
* must provide value	
eCRF completed date:	2021-11-05  Today Y-M-D
* must provide value	

Clinical trial participants

For patients who participate in a clinical trial of LA CAB+RPV at the time of the first data collection in EuroSIDA, please leave the date field blank and enter the data as soon as the trial is completed.

Demography	
Date of birth:	1990-11-05  Y-M-D
* must provide value	
Trial history	
Has the patient ever participated in a clinical trial of long-acting cabotegravir and/or rilpivirine?	<input type="radio"/> No <input checked="" type="radio"/> Yes <input type="radio"/> Unknown
*must provide value	reset
Is the trial still ongoing?	<input type="radio"/> No <input checked="" type="radio"/> Yes <input type="radio"/> Unknown
*must provide value	reset
Date of last injection of long-acting cabotegravir and/or rilpivirine within the clinical trial period (please enter as soon as the trial is completed):	<input type="text"/>  Today Y-M-D
*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? <small>*must provide value</small>	<input type="radio"/> No <input checked="" type="radio"/> Yes <input type="radio"/> Unknown
Drug (1): <small>*must provide value</small>	<div> <input type="text"/> <div> <div></div> <div>CAB: Cabotegravir</div> <div>RIL: Rilpivirine</div> </div> </div>
Start date(1): <small>*must provide value</small>	<input type="text"/> <div> <div>31</div> <div>Today</div> <div>Y-M-D</div> </div>
Stop date(1): <small>*must provide value</small>	<input type="text"/> <div> <div>31</div> <div>Today</div> <div>Y-M-D</div> </div>

Oral lead-in antiretroviral therapy transition

If oral lead-in therapy was stopped because long-acting antiretroviral therapy was started, the section for the first injection will appear (see below). 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 lead-in therapy 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? <small>*must provide value</small>	<input type="radio"/> No <input checked="" type="radio"/> Yes <input type="radio"/> Unknown
Drug (1): <small>*must provide value</small>	
Start date(1): <small>*must provide value</small>	
Stop date(1): <small>*must provide value</small>	
Was oral lead-in antiretroviral therapy stopped because the patient has initiated long-acting antiretroviral therapy? (1)	
Reason for discontinuation (1):	<div> <div>Treatment failure (i.e. virological, immunological and/or clinical failure)</div> <div>Virological failure</div> <div>Partial virological failure</div> <div>Resistance (based on test result)</div> <div>Abnormal fat redistribution</div> <div>Concern of cardiovascular disease</div> <div>Dyslipidaemia</div> <div>Cardiovascular disease</div> <div>Concern about weight gain</div> <div>Hypersensitivity reaction</div> <div>Hypersensitivity reaction - Allergic reaction</div> <div>Hypersensitivity reaction - Anaphylactic reaction</div> <div>Injection site reaction</div> <div>Injection fatigue (not related to safety)</div> <div>Toxicity, predominantly from abdomen/GI tract</div> <div>Toxicity - GI tract</div> <div>Toxicity - Liver</div> <div>Toxicity - Pancreas</div> <div>Toxicity, predominantly from nervous system</div> </div>

Hepatotoxicity Event Reporting

If lead-in therapy was stopped due to hepatotoxicity, please complete the “EuroSIDA hepatotoxicity event form” in REDCap. A link will take you directly to the form.

Reason for discontinuation (1):	<input type="text" value="Toxicity - Liver"/>
<p>Please fill in the EuroSIDA hepatotoxicity event form</p> <p>Open EuroSIDA hepatotoxicity event form</p> <p>Note: Clicking the link will open a new window, allowing you to continue entering data.</p>	

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 12, 24, 36 and 48 months after switching regimens. 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) <small>*must provide value</small>	<input type="radio"/> No <input checked="" type="radio"/> Yes <input type="radio"/> Unknown
Date of most recent resistance test prior to initiation of long-acting antiretroviral therapy (1) <small>*must provide value</small>	<input type="text" value="2020-10-05"/> <input type="button" value="Today"/> Y-M-D
Please upload a copy of the resistance test report (1)	<input type="button" value="Upload file"/>
HIV resistance testing after virological failure of long-acting cabotegravir + rilpivirine	
eCRF section completed by:	<input type="text"/>
eCRF section completed date:	<input type="text"/> <input type="button" value="Today"/> Y-M-D
If the patient has discontinued long-acting cabotegravir + rilpivirine, has an HIV resistance test been performed? <small>*must provide value</small>	<input type="radio"/> No <input type="radio"/> Yes <input type="radio"/> Unknown

Form Status

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

Form Status	
Complete?	<input type="button" value="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? <small>*must provide value</small>	<input type="button" value="H"/> <input type="text" value="Long acting cabotegravir + long acting rilpivir"/>
Dosage long acting cabotegravir: <small>*must provide value</small>	<input type="button" value="H"/> <input type="text" value="600mg"/>
Dosage long acting rilpivirine: <small>*must provide value</small>	<input type="button" value="H"/> <input type="text" value="900mg"/>
Date of first injection: <small>*must provide value</small>	<input type="button" value="H"/> <input type="text" value="2021-10-05"/> <input type="button" value="31"/> <input type="button" value="Today"/> <input type="text" value="Y-M-D"/>
Intended dosing schedule of long-acting antiretroviral therapy <small>*must provide value</small>	<input type="button" value="H"/> <input type="text" 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.

Next injection

Editing existing Center/patient code: 1111111	
Center/patient code:	1111111
First injection date:	<input type="text" value="2021-11-05"/>
Has the patient received the next planned injection with long-acting antiretroviral drugs <small>*must provide value</small>	<input type="radio"/> No <input checked="" type="radio"/> Yes <input type="radio"/> Unknown
Which long-acting antiretroviral drugs were given? <small>*must provide value</small>	<input type="text" value="Long acting cabotegravir + long acting rilpivir"/>
Dosage long acting cabotegravir: <small>*must provide value</small>	<input type="text" value="400mg"/>
Dosage long acting rilpivirine: <small>*must provide value</small>	<input type="text" value="600mg"/>
Date of injection: <small>*must provide value</small>	<input type="text"/> <input type="button" value="Today"/> <input type="button" value="Y-M-D"/>
Form Status	
Complete?	<input type="text" value="Incomplete"/>

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.

Editing existing Center/patient code: 1111111

Center/patient code: 1111111

First injection date: 2021-11-05

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

☒ No
☐ Yes
☐ Unknown

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

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 started bridging therapy?
*must provide value

☒ No
☐ Yes
☐ Unknown

Has the patient later restarted long-acting antiretroviral therapy?
*must provide value

☐ No
☐ Yes
☐ Unknown

If a decision to stop long-acting 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?
*must provide value

☒ No
☐ Yes
☐ Unknown

Reasons for discontinuation:
*must provide value

New injection form access

There are several ways to open a new injection form: by selecting “+Add new”. See below:

Data Collection Instrument	Status
EuroSIDA Event Form for use of long-acting cabotegravir+rilpivirine	Red status icon
Next injection	Green status icon with '+ Add new' button and red '2'
Assessment After Virological Failure	Grey status icon
Status	Grey status icon

Repeating Instruments

Next injection (2)	Status
1	Green status icon
2	Green status icon with '+ Add new' button and red '2'

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