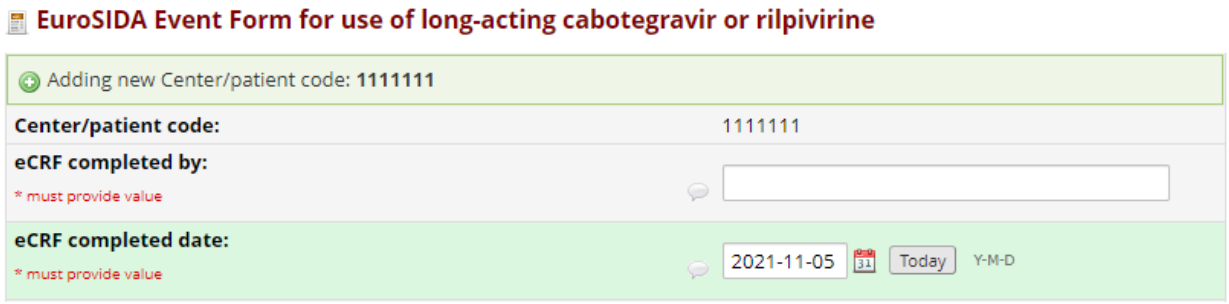
Manual of operations for the EuroSIDA Event Form for use of long-acting cabotegravir+rilpivirine electronic case report form (eCRF)

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.

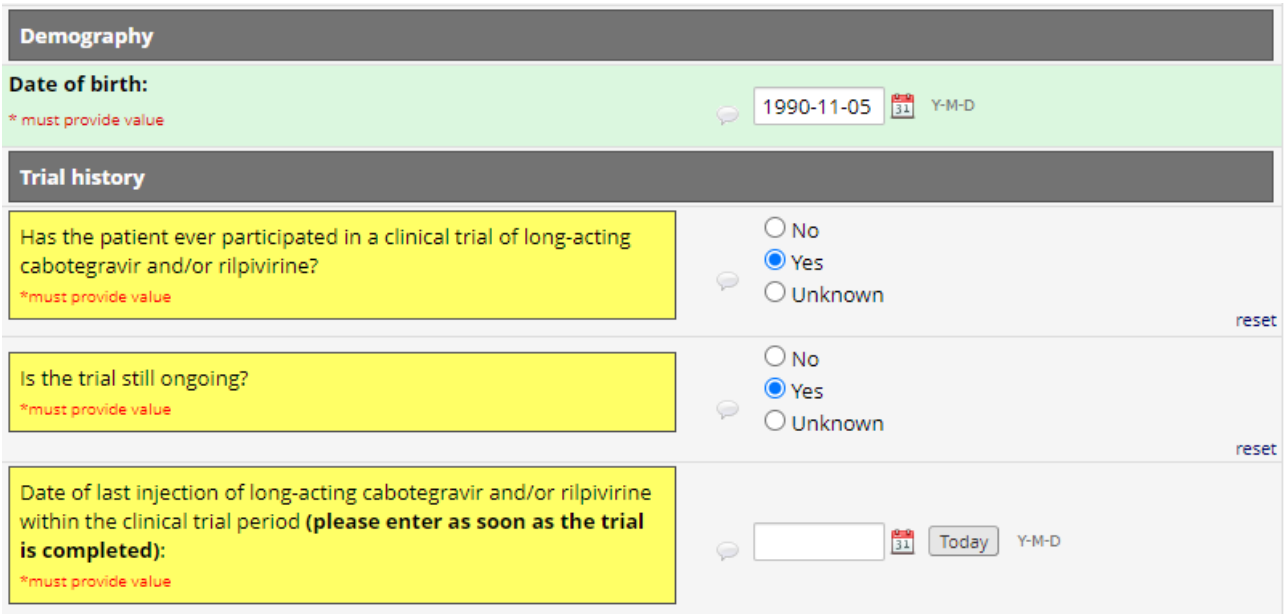
eCRF completion requirements: Name and date

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



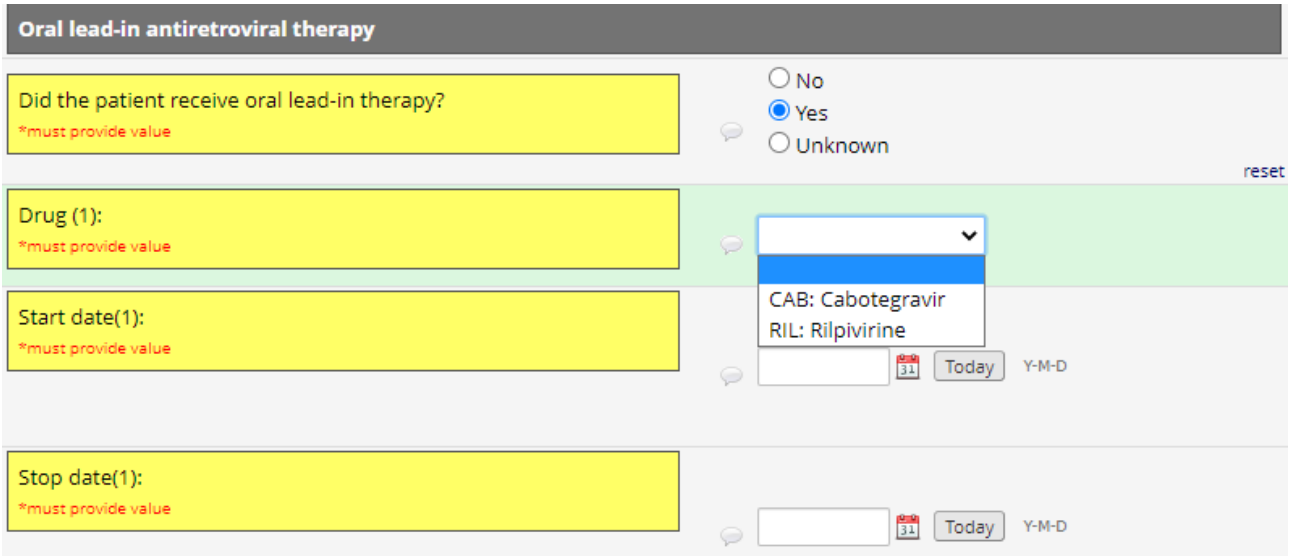
Clinical trial participants

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.



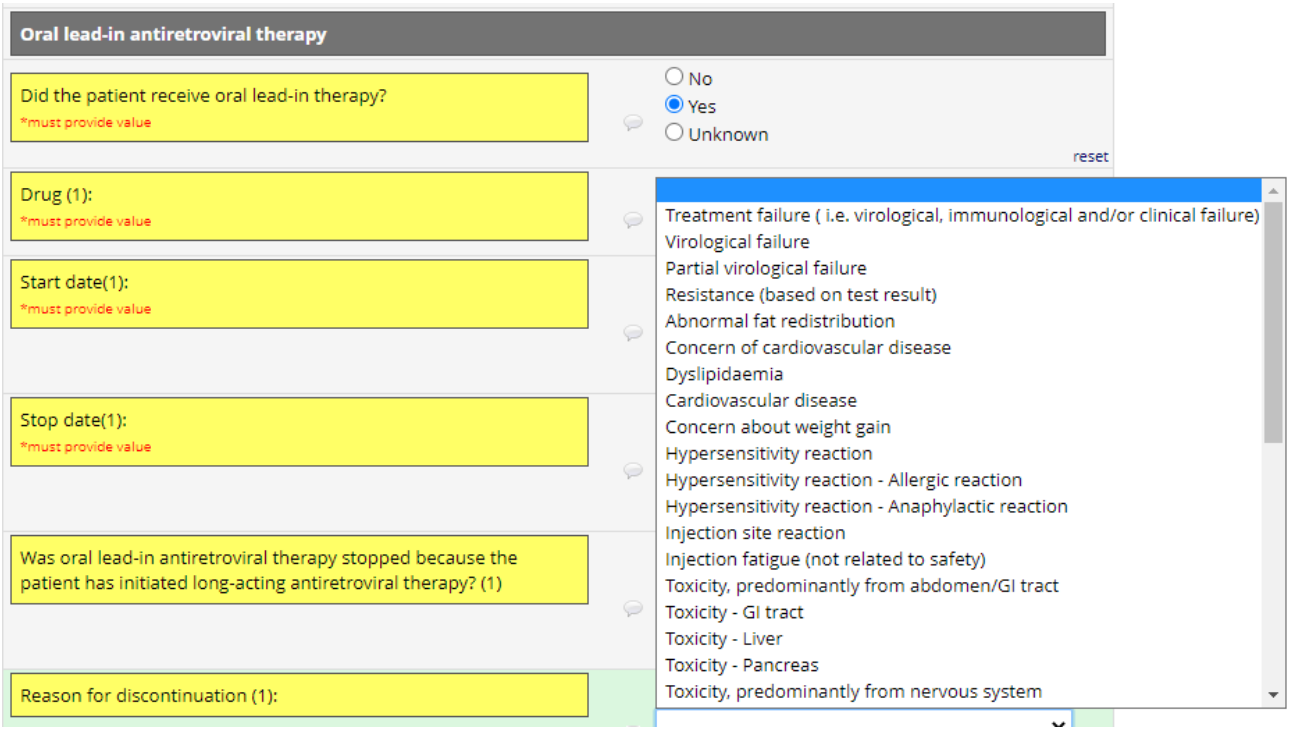
Oral lead-in antiretroviral therapy

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



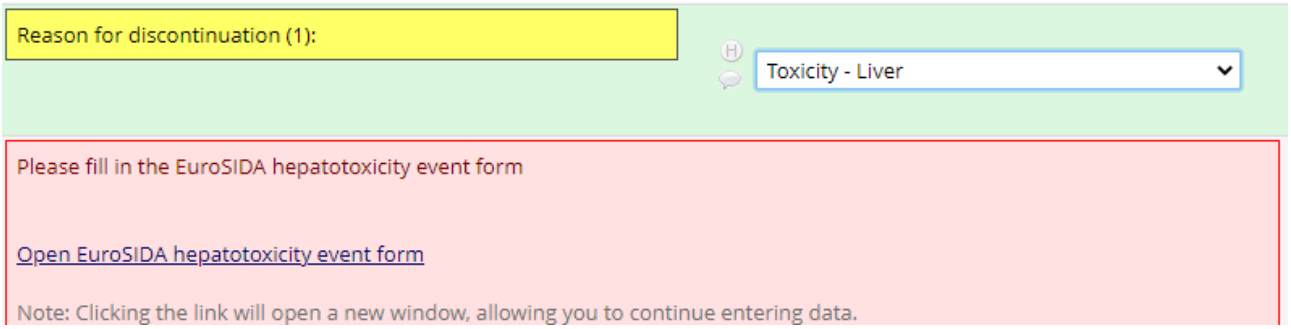
Oral lead-in antiretroviral therapy transition

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.



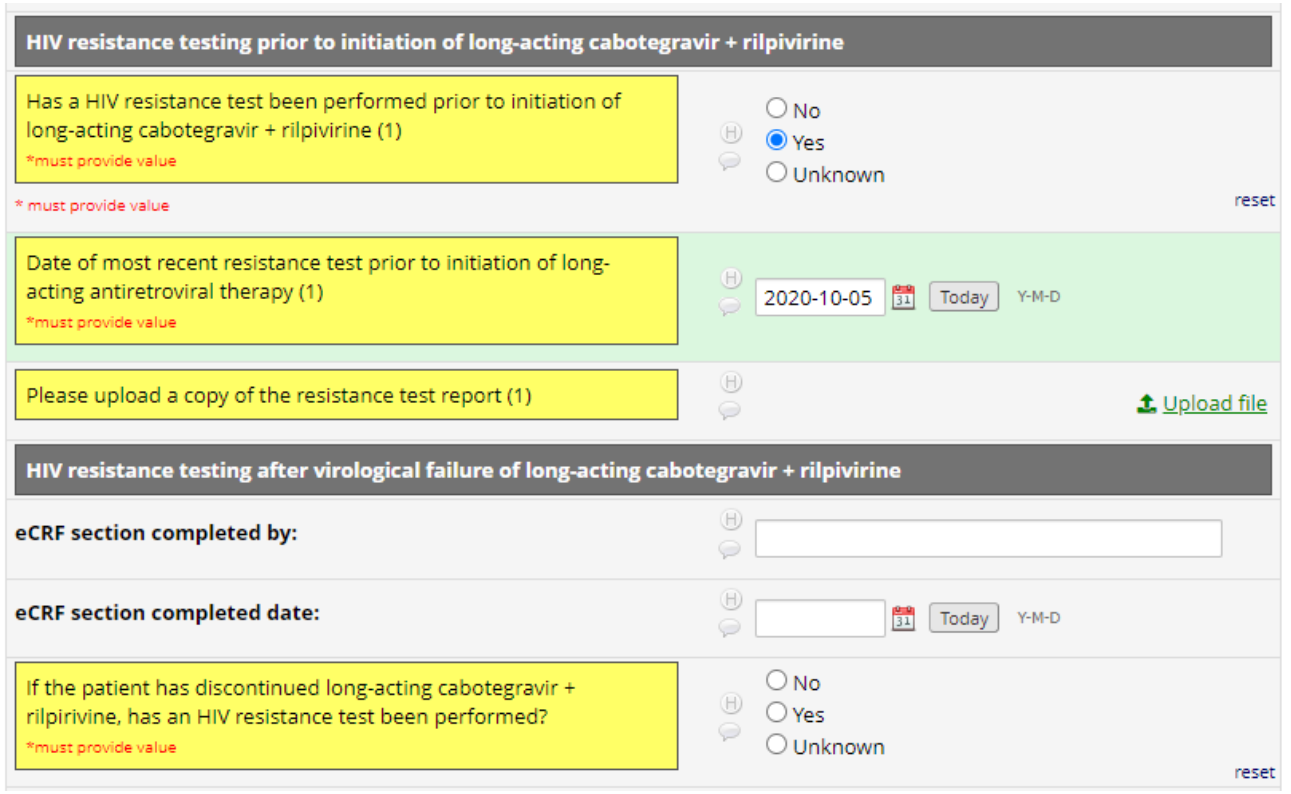
Hepatoxicity Event Reporting

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.



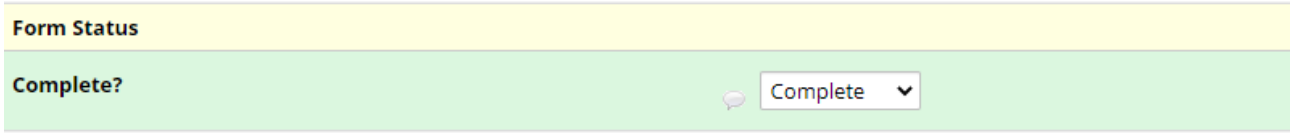
HIV Resistance Resting Collection

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.



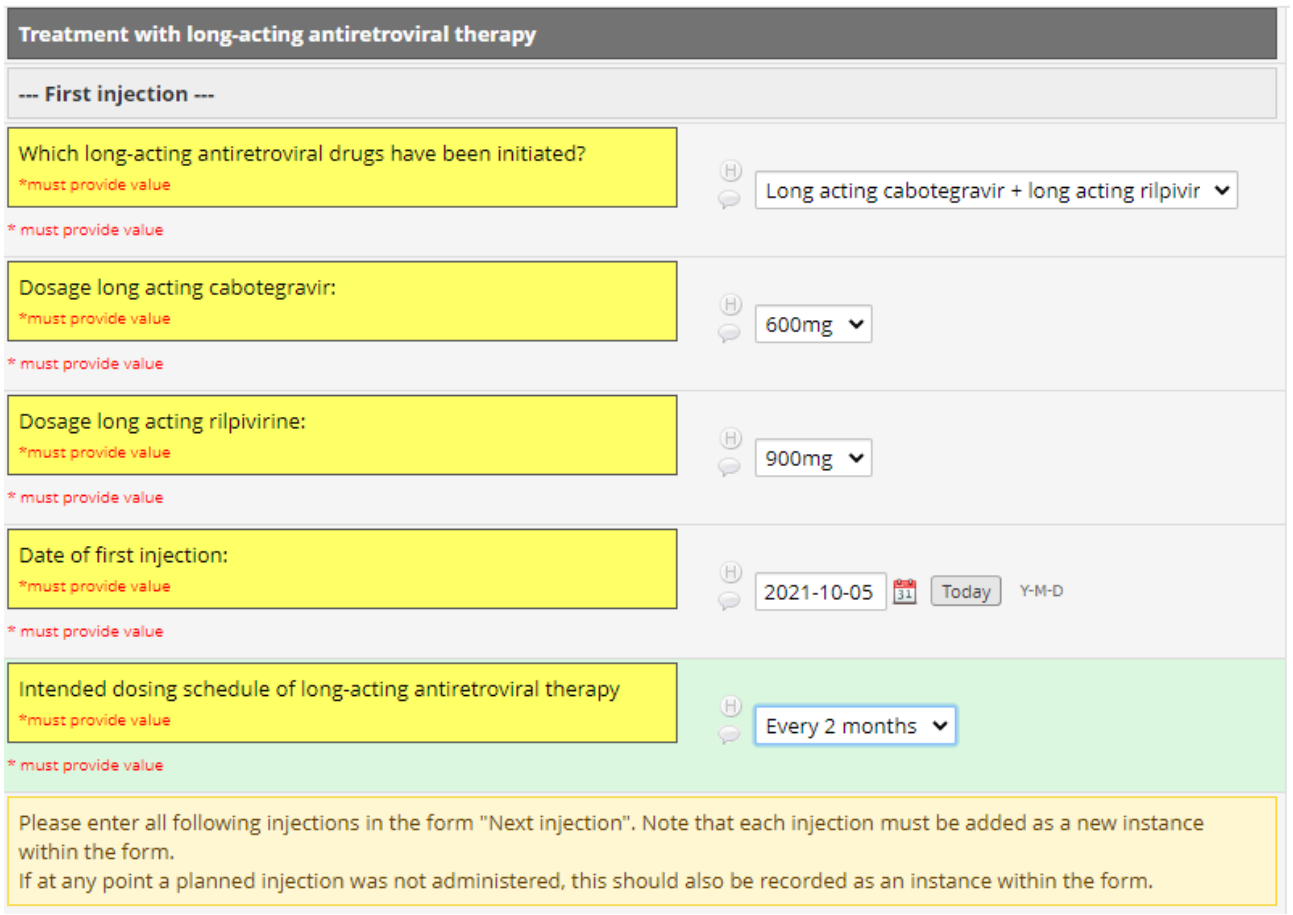
Form Status

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



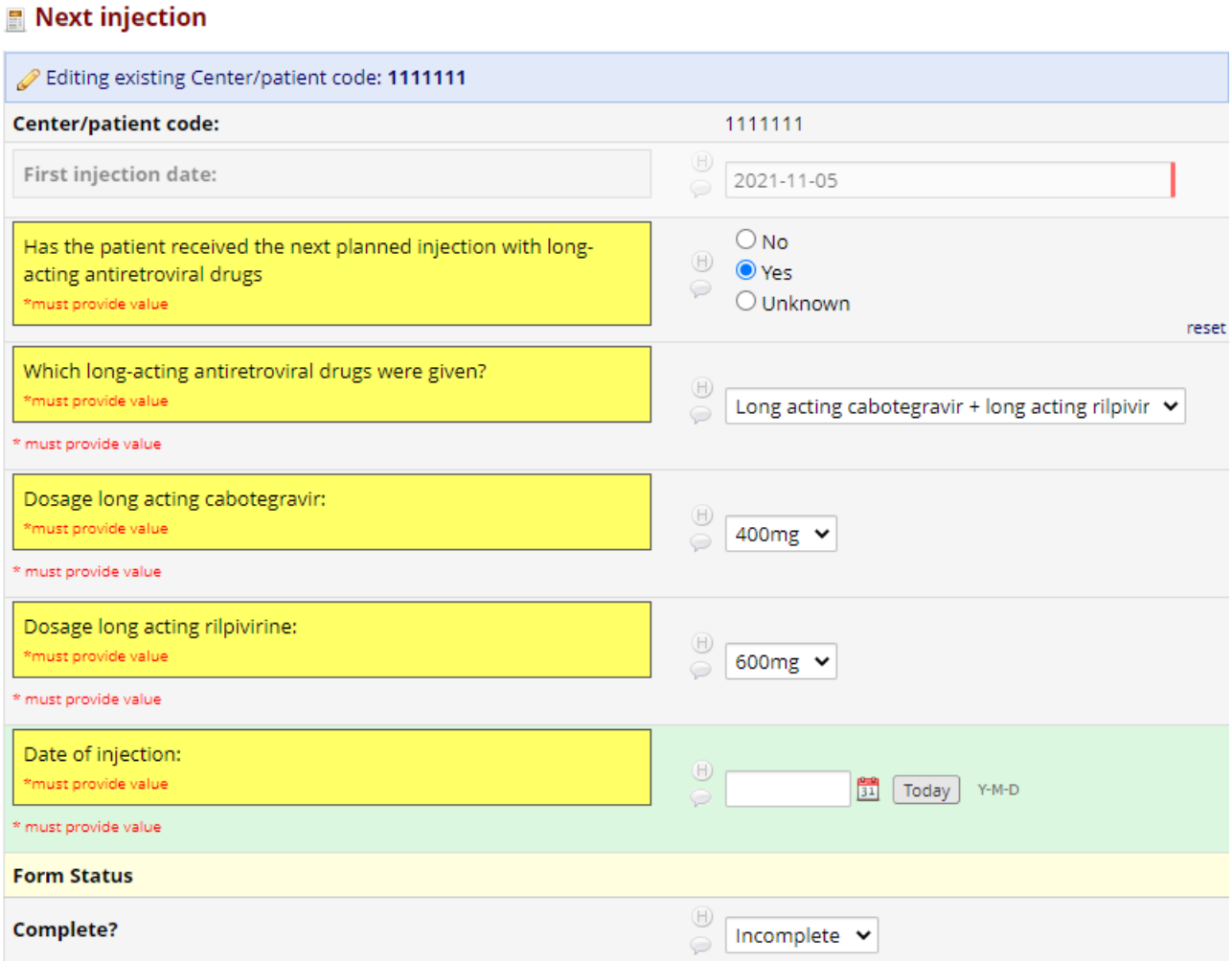
Injection and Dosage documentation

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.



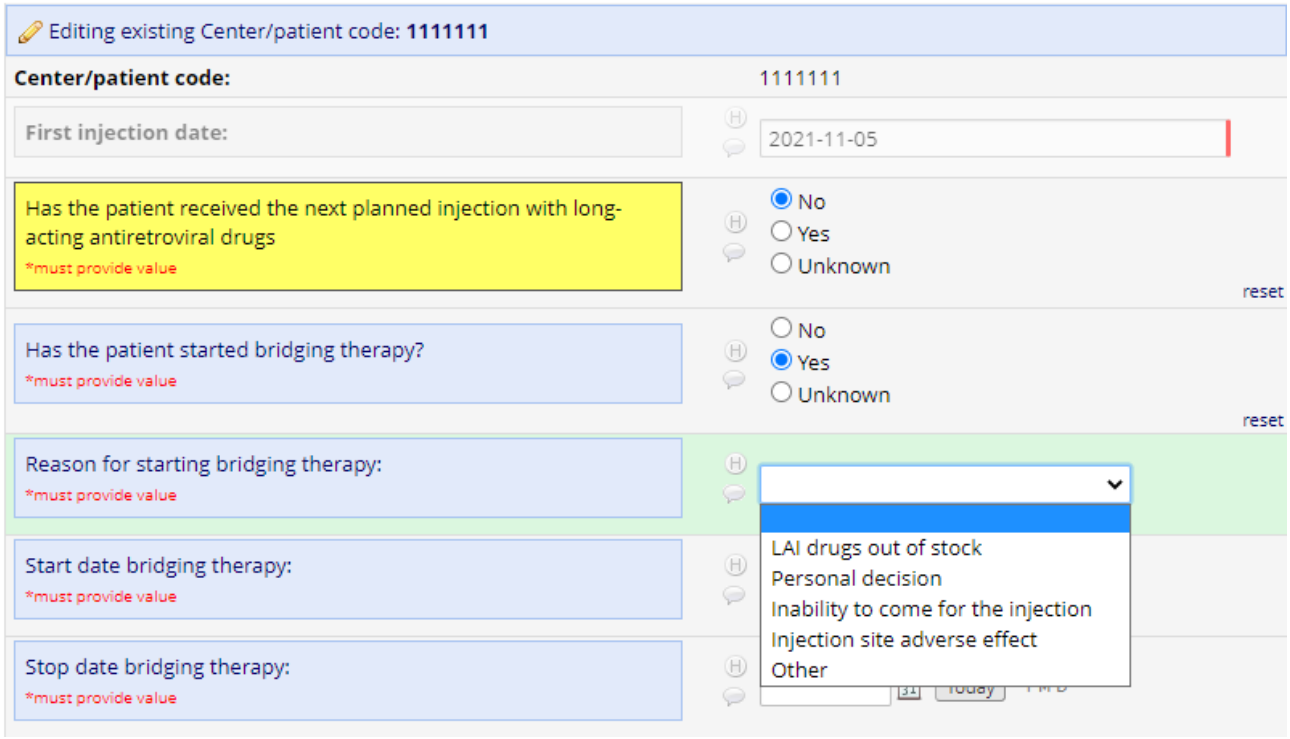
Reporting subsequent injections

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.

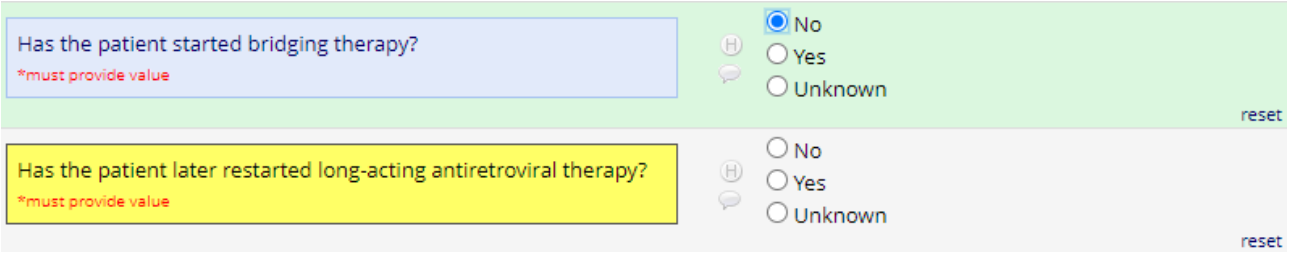


Oral bridging therapy

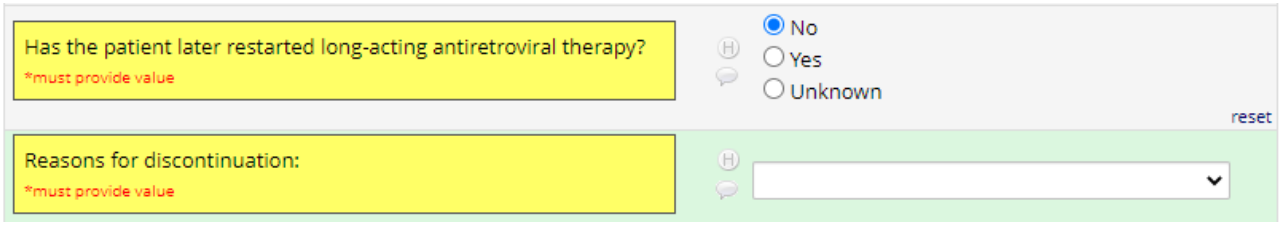
If the patient did not receive the next planned injection, you will be asked whether oral bridging therapy was given, and if yes, please choose a reason for starting bridging therapy.



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.

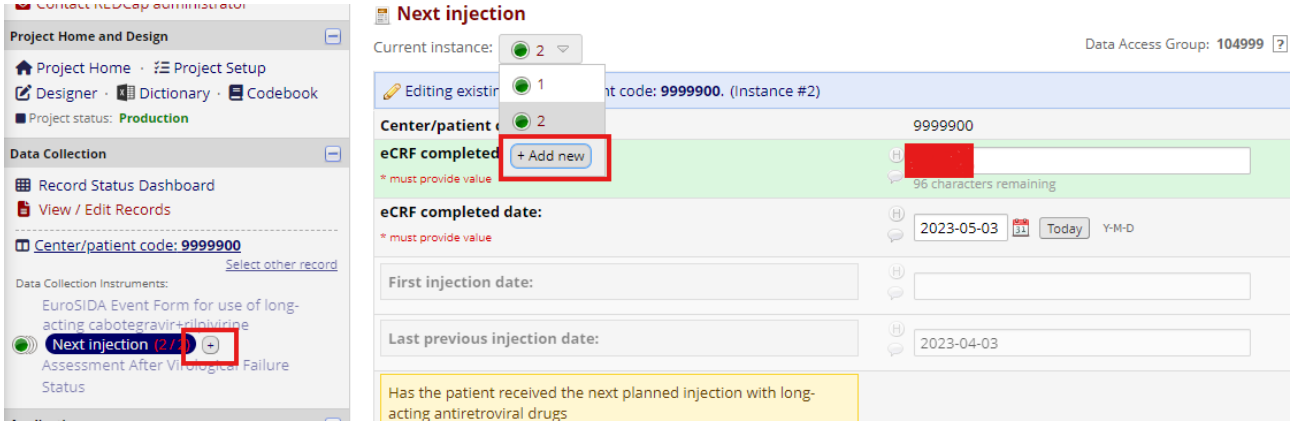


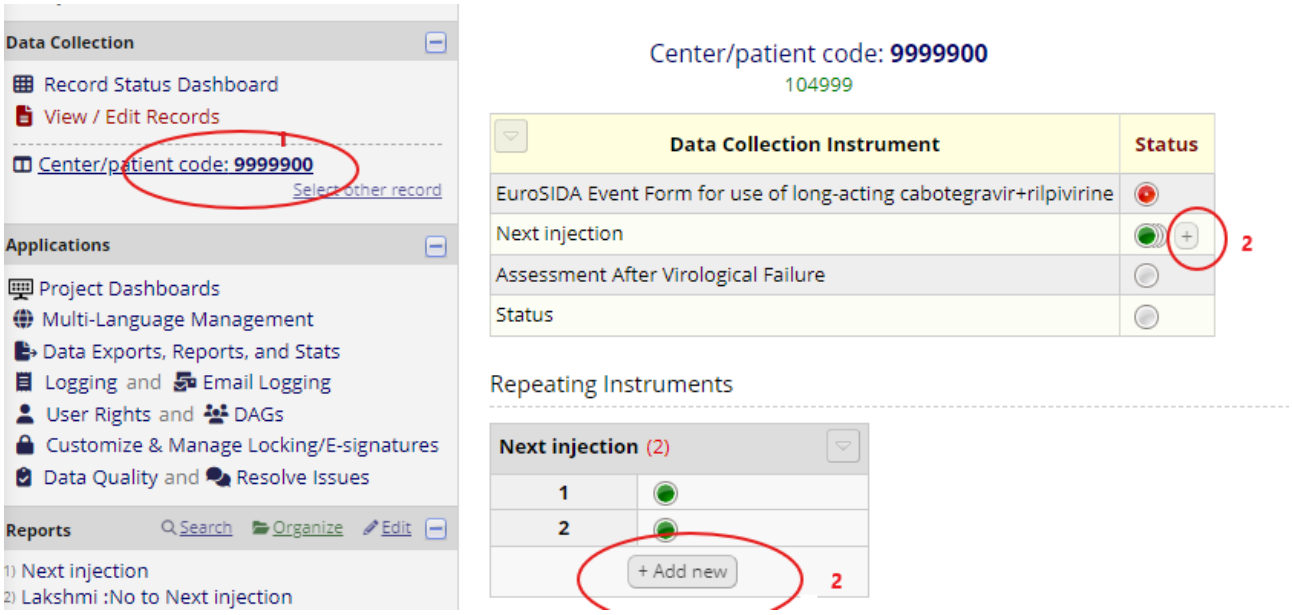
If a decision to stop long-acting therapy has been made, please select “No” and the reason for discontinuation. If a decision on whether or not to restart long-acting therapy has not been made, please select “Unknown” (this should later be changed to No or Yes, in case therapy is stopped or restarted,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



New injection form access

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





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