Django – The SHCS data entry tool for eCRFs
-A short introduction-

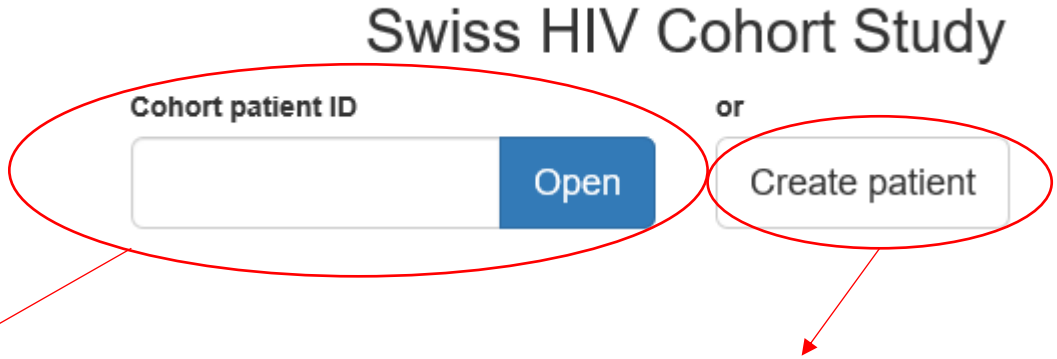
The SHCS data entry tool allows you to enter and review your patient's follow-up visits electronically. Please use the following link to write data directly into the SHCS database:

https://data.shcs.ch/accounts/login/?next=/

You can test the functionality using the following link. The data you enter into the test database **will not be saved**. This is just to test the system:

https://test.data.shcs.ch/accounts/login/?next=/

1) Find existing / Create new patient



Enter/review follow-up:

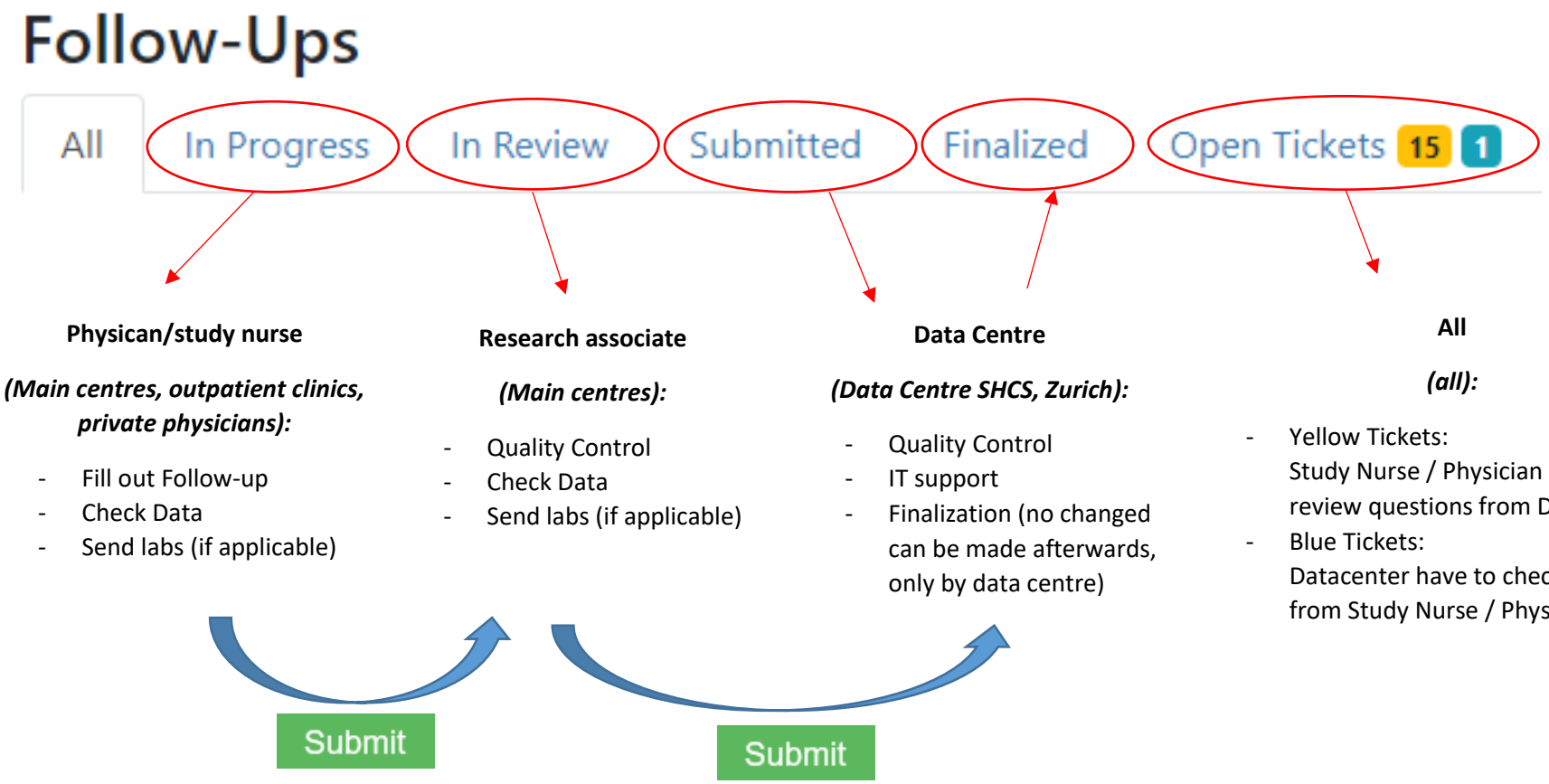
Enter the ID number to find the patient's previous follow-ups or to enter a new follow-up.

Register a new patient:

The system creates a new ID. Every center got a special range of numbers for new IDs created by the system. Once the system has created a new ID, it will never be used again. Please do not use these IDs for patients registered on paper.

2) Main Page overview

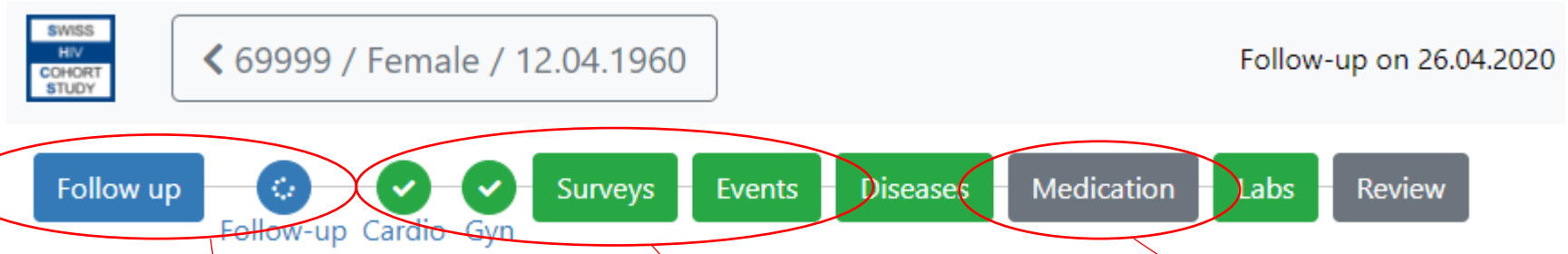
In order to maintain the high data quality, a stepwise procedure is necessary. In the graphic below, you can see the steps a follow-up has to go through in detail:



Before submitting a follow-up, please check the data and send/enter the laboratories!

3) Follow Up

When you entered a FUP you will have an overview over all sections needed to be filled out.



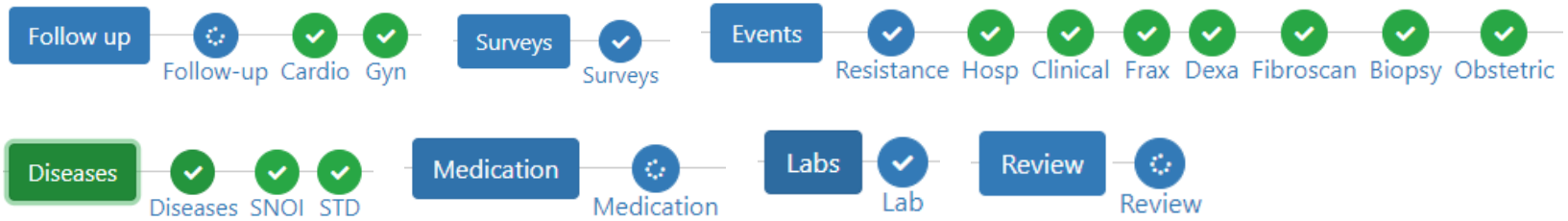
The Blue lighted section is where you are at the moment

The green lighted sections are complete

The grey lighted sections are not complete and must be completed before finalize the FUP

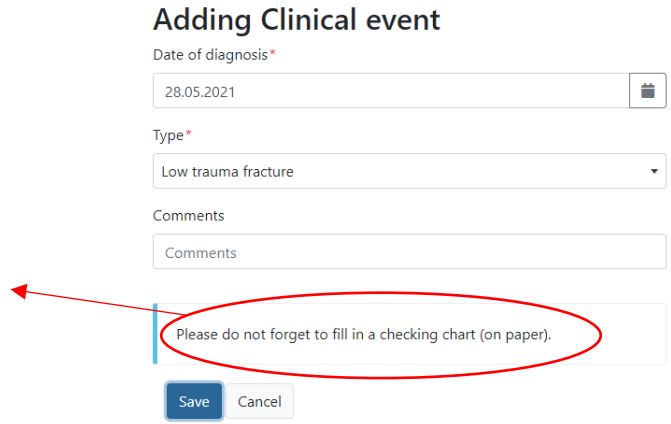
3.1) Follow up structure

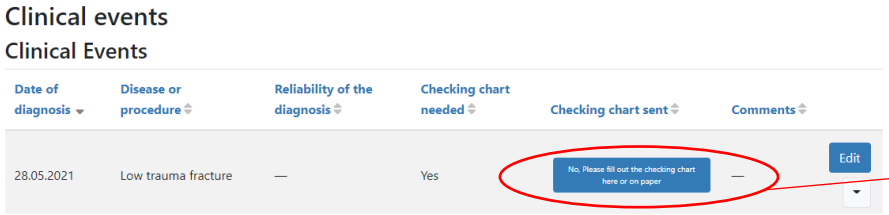
The sections are structured as following:



3.2) Checking Chart / CoDe forms – SOON AVAILABLE!

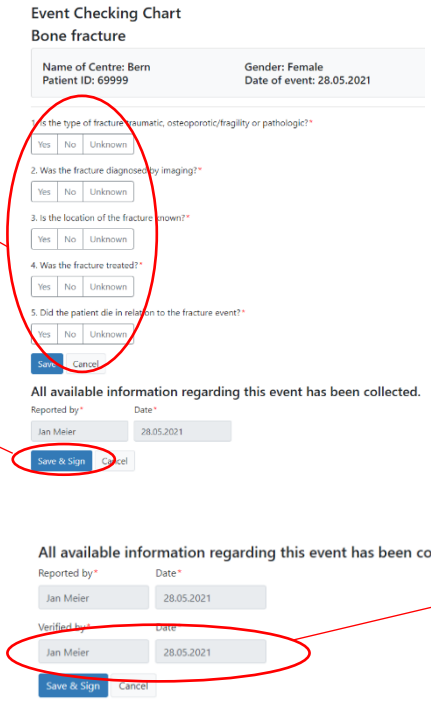
Step1: If there is a Clinical Event/Disease or Death which requires a Checking Chart / CoDe form, you will see this comment after entering the Clinical Event/Disease as following:





Step2: To fill in the Checking Chart you have to click this Button now

Step3: Please fill in all required data



Step4: click on “Save and sign” which makes you the first person which is responsible for this Checking Chart, a second person (a Physician) is required to commit the data in the Checking Chart

Step5: Now a second person (a Physician) needs to double check the data. For this step, the Physician can access to the Checking Chart as mentioned here on in **section 5.7)** in this introduction. The Physician has to check the data and if everything is fine, click on “save and Sign”. After the first person signed there will be a second person to sign automatically. Now the Checking Chart is submitted and finished.

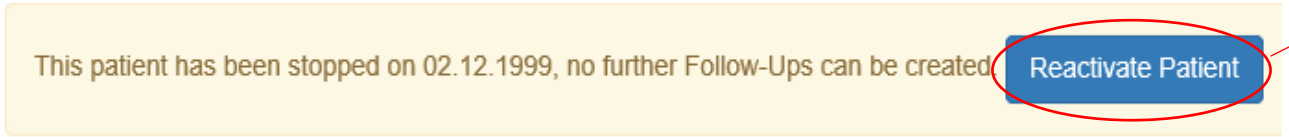
4) Stop and re-activate Patients

You need to access the patient as mentioned in step 1) to see following options:

Stop a patient:

When you stop a patient, the latest follow-up will open up. In the follow-up you have the possibility to add missing information about the patient during the period between the last follow-up and now.

You will see the stop in the patient overview e.g. "In review" and you can adapt it until you have submitted it to the data centre.



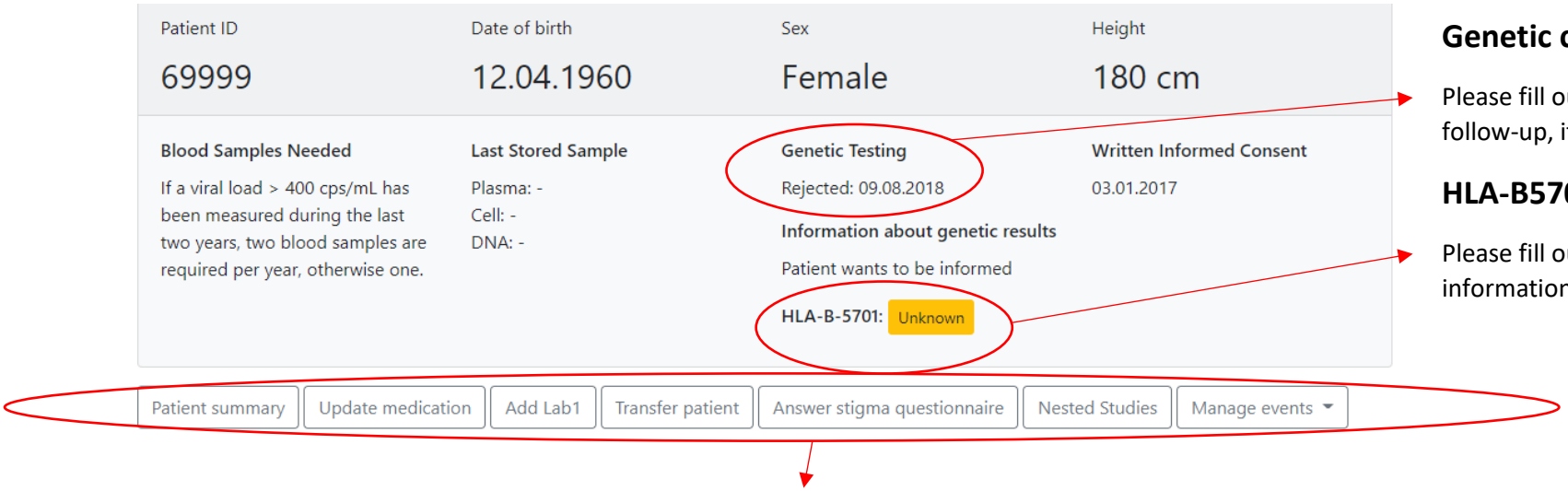
Reactivate a patient:

It is possible to reactivate a stopped patient under certain conditions. Please search for the ID and click on “reactivate patient”. If applicable, send the new consent date to the data centre.

5) Patient options: overview

You need to access the patient as mentioned in step 1) to see the following page.

Here you have a quick overview about the patient.



Genetic consent:

Please fill out the genetic consent field in the follow-up, if this information is missing.

HLA-B5701:

Please fill out the HLA-B5701, if this information is missing.

All these points are described in detail on the following pages. You have also a quick overview to the patient data as you see in the picture above.

5.1) Patient summary

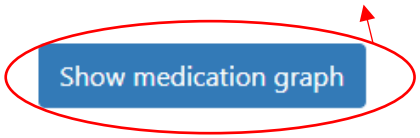
The Patient Summary button will lead you to the summary page of this patient.

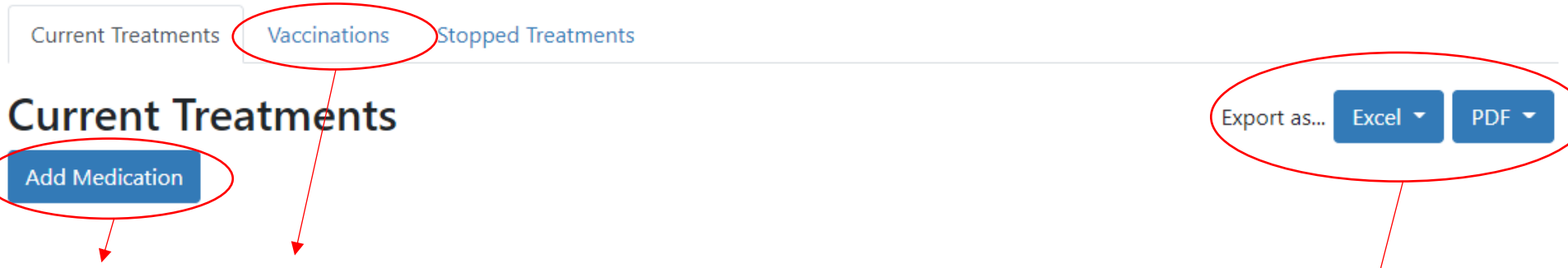
You can see the following values on this page:

A) HIV-Pos date and Registration date
B) The Graph for CD4 cells and HIV-RNA
C) The latest Serology results
D) The CHD Risk Profile
E) Disease history
F) Clinical Events history
G) LAB1 history
H) Current ART
I) Medication history

5.2) Update Medication

You can view the medication graph on this page





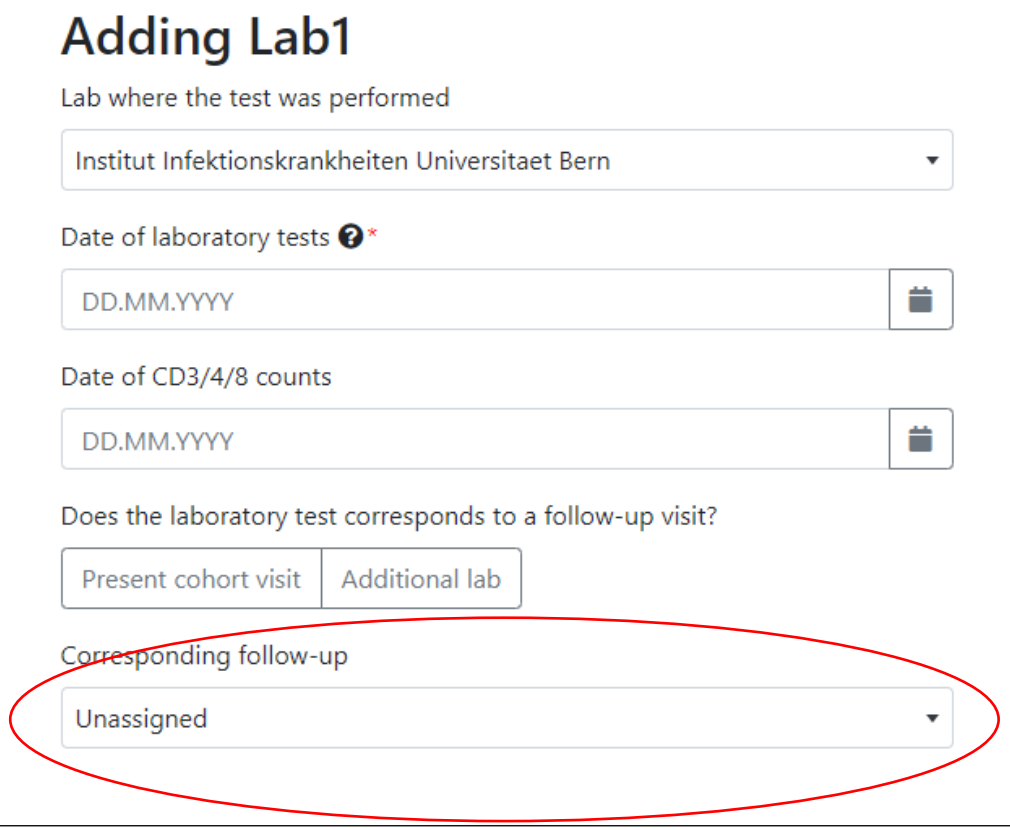
In this section you can update the medication,

treatment and vaccination also when all FUP are finalized.

You can also export data as PDF or Excel File

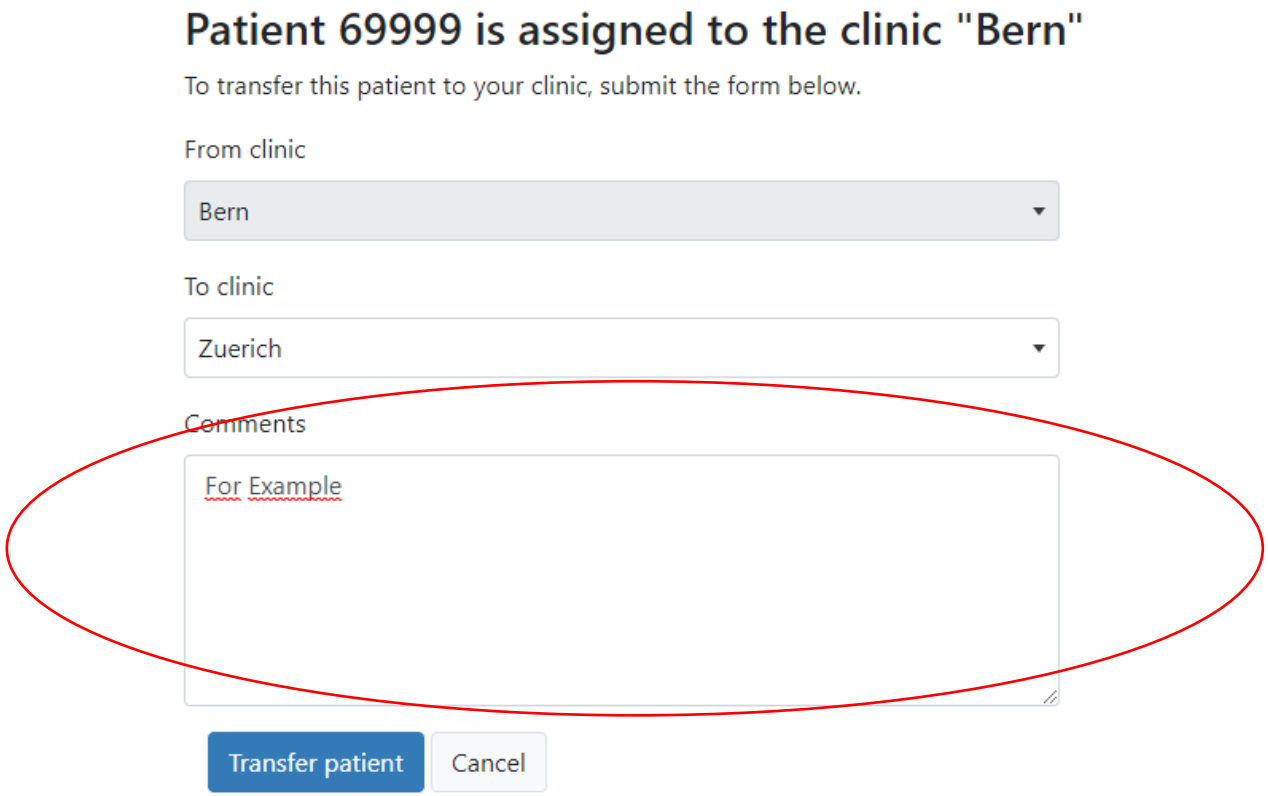
5.3) Add Lab1

Here you can Add a new LAB1 when no FUP is open. There is an option to assign the LAB1 to an existing FUP, which is the best option if it's an additional LAB1. You can just assign the new LAB1 to the latest FUP. If it is the LAB1 which is related to the next FUP which is not opened due to some reason you can choose the option "unassigned" and you can assign the LAB1 as soon as the new FUP is opened.



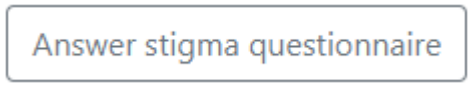
5.4) Transfer Patient

If you want to transfer a patient ID from another center to your own, please fill out the transfer request.



Please fill in a short comment about the reason of transferring the patient.

5.5) Stigma Questionary



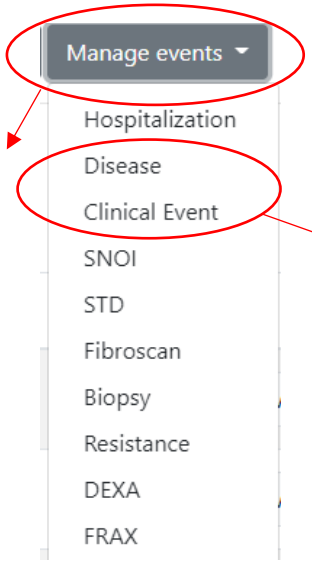
In this section you can enter the STIGMA questionary at any time, no open FUP is needed here. If the Patient doesn't need to answer the STIGMA questionary this button will disappear. As long as you can see this button, the patient should answer the STIGMA questionnaire as soon as possible.

5.6) Nested Studies – PILOT PHASE (limited access)

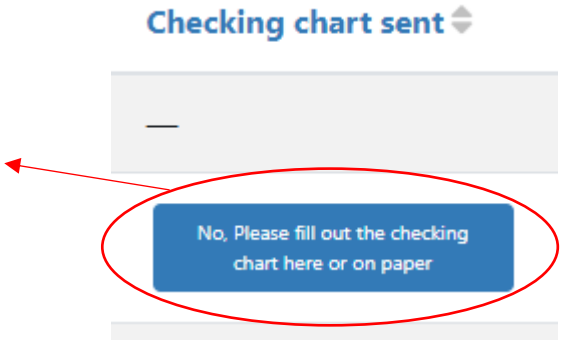
This is a list of the studies in which this patient could participate.

5.7) Manage Events and Checking Charts

In This Drop-Down you can chose the Event you want to manage as mention in the picture on the right. You can change the data which is entered for a not finalized FUP but not for finalized FUPs. You can also add new events without an open FUP at any time. All these Events have theyre own date, so you don't need to assign the Event to a FUP.



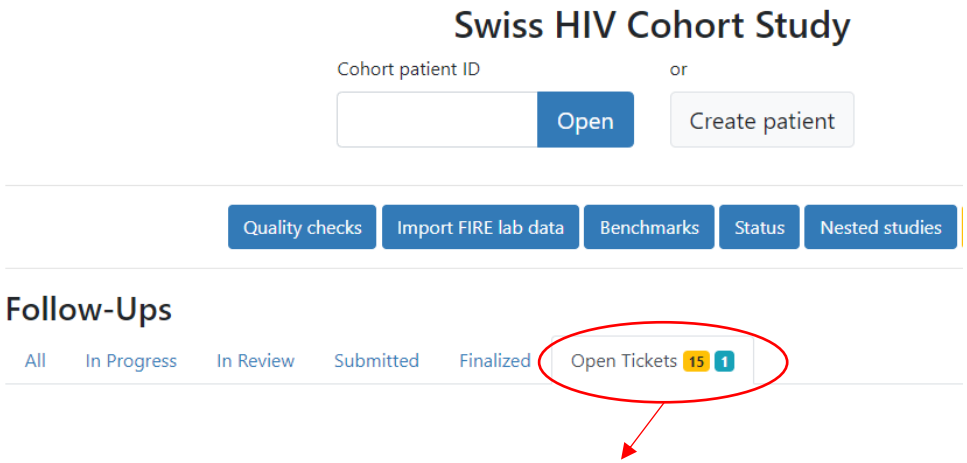
When you access the Events "clinical" or "Disease" you can see if there is any new Checking Chart needed. If yes you can fill in the Checking Chart directly in Django. Please note it must be re-viewed and signed from a doctor and a study nurse.



6) Tickets

The Tickets are an option to communicate between the Physician/ Studynurse and the Datacenter. Most likely the tickets are used from the Datacenter to ask something about a FUP which was submitted to the Datacentre. This could be all questions about missing values, unusual values, blood samples or anything else.

6.1) Manage all open Tickets



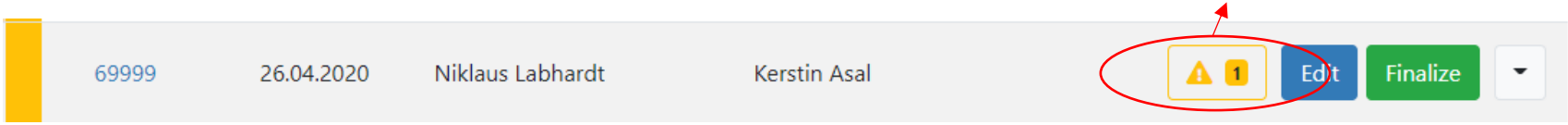
You can see all open Tickets which are related to your User Profile here on the main page

Yellow Tickets means its the Physicians / Study Nurses turn to have a look at it

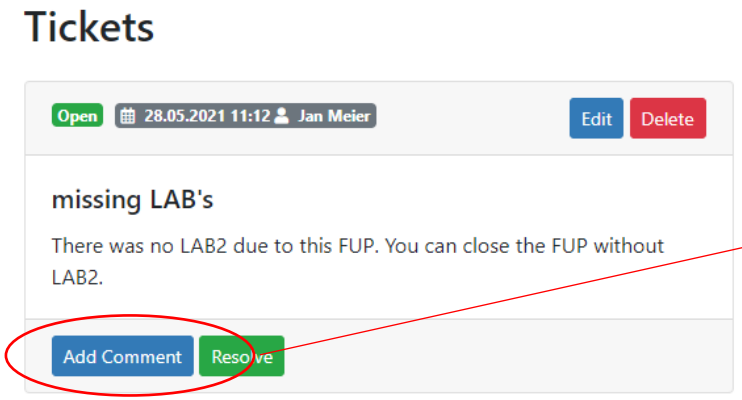
Blue Tickets means it is the Datacentres' turn to have a look at it

6.2) Answer an open Ticket

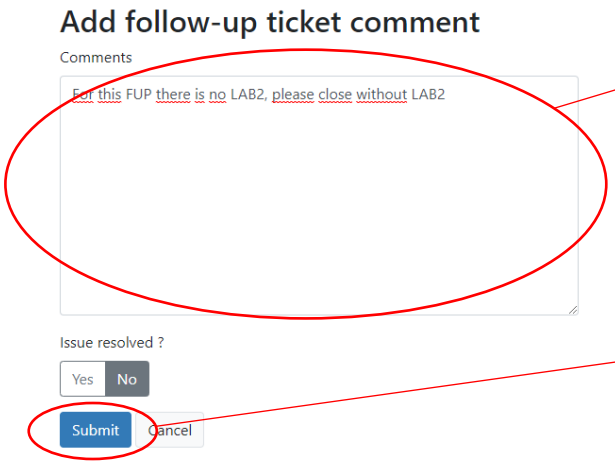
Step 1: Click on the yellow Ticket



Step 2: now you see the ticket



Step 3: Click on “Add Comment” to answer the ticket

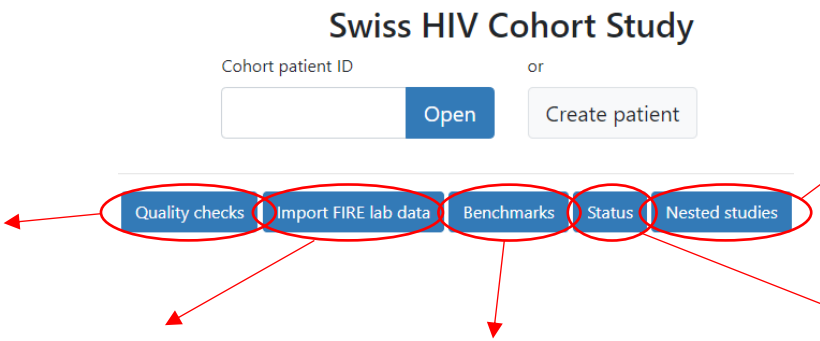


Step 4: write your comment to the Ticket

Step 5: submit your Feedback back to the Datacenter

7) General Sections

On the Mainpage you can also see following sections:



Here you can have a look at all nested studys from the SHCS. You find the active participant patient and also the study

Here you find access to the Quality Checks, these section will be descripted later on in **7.1)**

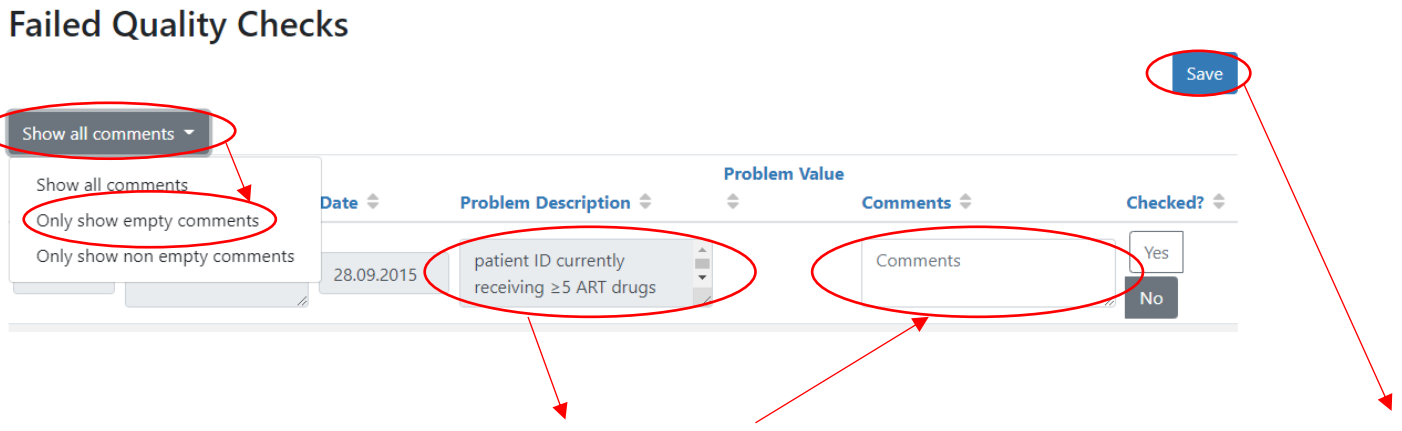
In this section you can have an overview and you are able to manage your overdue patients, unsubmitted FUPs, Checking Charts and CoDe forms, this will be explained in **7.2)**

This section is only relevant for the Datacentre

In this section you can compare your own patients with other patients included in the SHCS due to different variables. This can be very useful for Physician to see an overview of their patients

7.1) Quality Checks

Here you find all open quality checks. These are generated automatically by Django due to inconsistence data or unrealistic data entries in a FUP. When you enter this section you will see al quality checks related to your User-Profile. From time to time all these checks should be filled out.



Step1: to see just the new quality checks you can select "Only Show emty comments"

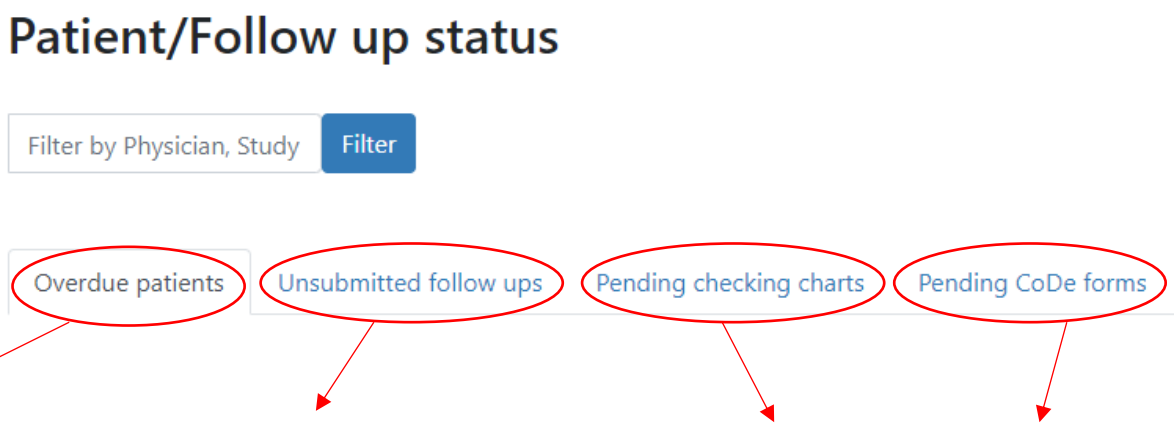
Step2: You can check the problem description and add you comment for it in the comment field

Step3: After all comments are written you can save this page and it will be the Datacentres turn to continue

7.2) Status

Status

Here you have a good overview over your patients and Checking Charts / CoDe forms.



Here you can find all patient which should already have a new FUP due to the SHCS Guidelines. You can also Stop the patients right here

Here you can find all FUPs which are not submitted to the Datacentre yet. You have a good overview and you can see all older FUPs which are still pending on one page sorted by Date. The sections is splitted to FUPs which are not submitted since 3-4 Months and FUPs which where not submitted for more than 4 Months

Here you can find all open Checking Charts and CoDe forms. You can easaly access these forms directly from this page and edit / finish these. Also the Physician sees all the checking charts and CoDe which he must double check and sign. The Checking Charts are splitted to “Disease” on top and “Clinical events” below.