

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

Swiss HIV Cohort Study

Cohort patient ID or

Enter/review follow-up:

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

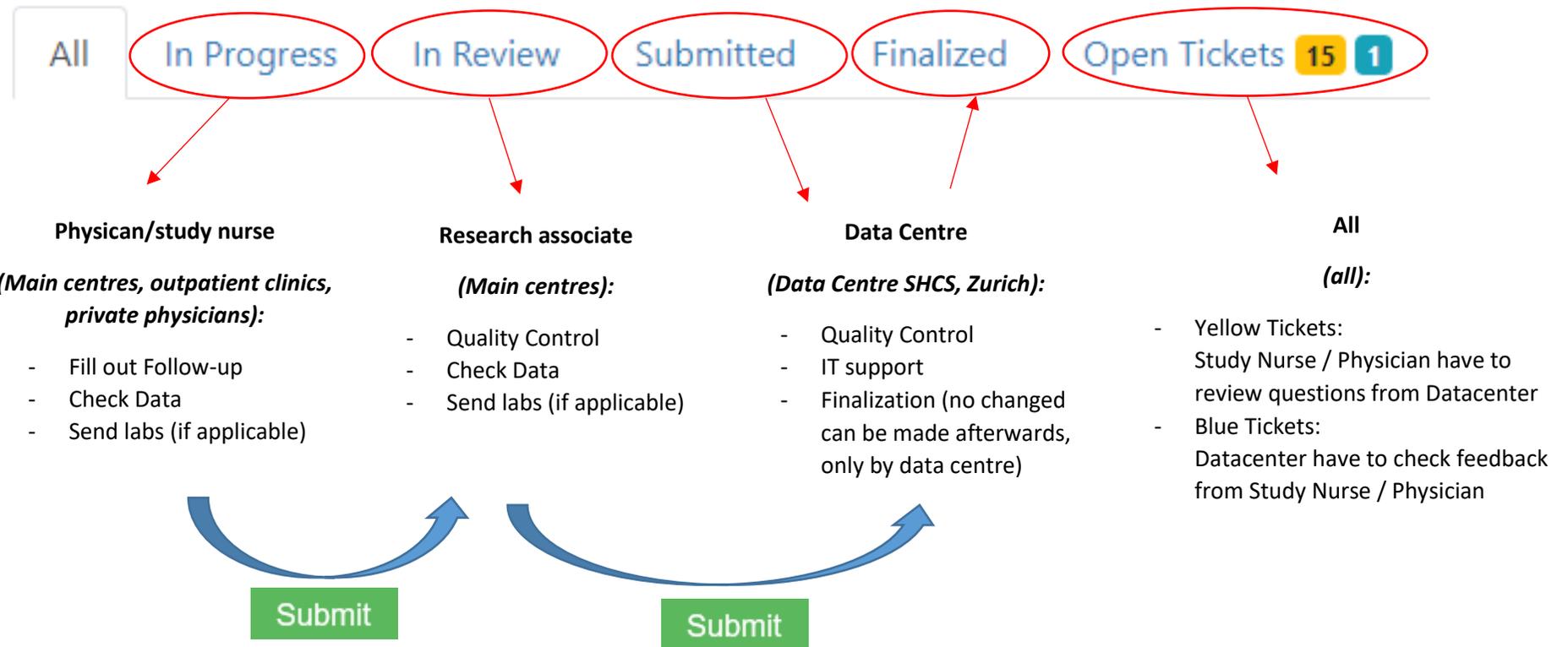
Register a new patient:

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:

Follow-Ups



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.



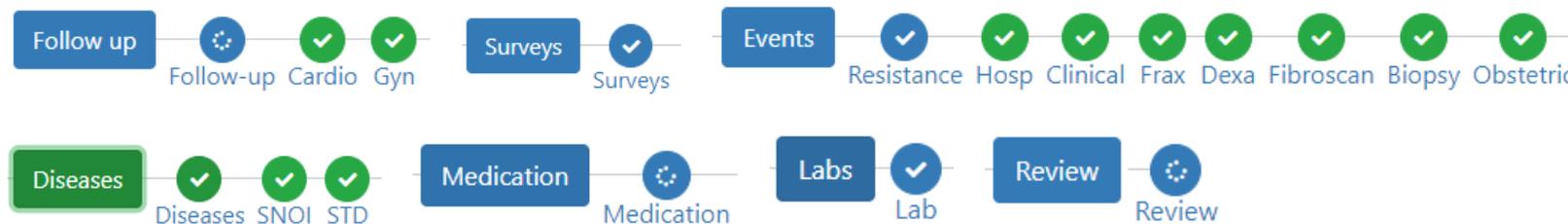
The Blue lighted section is where you are at the moment

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:

Adding Clinical event

Date of diagnosis*

Type*

Comments

Clinical events

Clinical Events

Date of diagnosis	Disease or procedure	Reliability of the diagnosis	Checking chart needed	Checking chart sent	Comments
28.05.2021	Low trauma fracture	—	Yes	<input type="button" value="No. Please fill out the checking chart here or on paper"/>	<input type="button" value="Edit"/>

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

Event Checking Chart

Bone fracture

Name of Centre: Bern
 Patient ID: 69999

Gender: Female
 Date of event: 28.05.2021

1. Is the type of fracture traumatic, osteoporotic/fragility or pathologic?*

2. Was the fracture diagnosed by imaging?*

3. Is the location of the fracture known?*

4. Was the fracture treated?*

5. Did the patient die in relation to the fracture event?*

All available information regarding this event has been collected.

Reported by*
 Jan Meier

Date*
 28.05.2021

All available information regarding this event has been collected.

Reported by*
 Jan Meier

Date*
 28.05.2021

Verified by*
 Jan Meier

Date*
 28.05.2021

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:

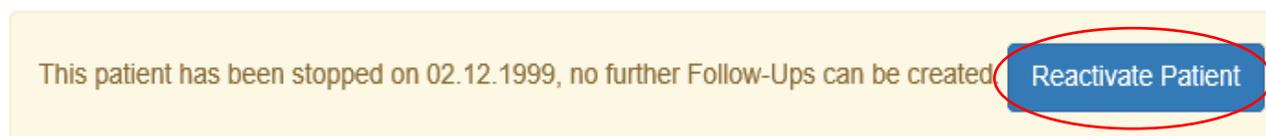
Follow-ups



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.

Patient ID	Date of birth	Sex	Height
69999	12.04.1960	Female	180 cm
Blood Samples Needed If a viral load > 400 cps/mL has been measured during the last two years, two blood samples are required per year, otherwise one.	Last Stored Sample Plasma: - Cell: - DNA: -	Genetic Testing Rejected: 09.08.2018 Information about genetic results Patient wants to be informed HLA-B-5701: Unknown	Written Informed Consent 03.01.2017

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.

Patient summary Update medication Add Lab1 Transfer patient Answer stigma questionnaire Nested Studies Manage events ▾

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.

5.2) Update Medication

Update medication

You can view the medication graph on this page

Show medication graph

Current Treatments Vaccinations Stopped Treatments

Current Treatments

Add Medication

In this section you can update the medication, treatment and vaccination also when all FUP are finalized.

Export as... Excel PDF

You can also export data as PDF or Excel File

5.3) Add Lab1

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.

Adding Lab1

Lab where the test was performed

Institut Infektionskrankheiten Universitaet Bern

Date of laboratory tests ?*

DD.MM.YYYY

Date of CD3/4/8 counts

DD.MM.YYYY

Does the laboratory test corresponds to a follow-up visit?

Present cohort visit Additional lab

Corresponding follow-up

Unassigned

5.4) Transfer Patient

Transfer patient

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

Patient 69999 is assigned to the clinic "Bern"

To transfer this patient to your clinic, submit the form below.

From clinic

Bern

To clinic

Zuerich

Comments

For Example

Transfer patient Cancel

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

5.5) Stigma Questionary

Answer stigma questionnaire

In this section you can enter the STIGMA questionnaire at any time, no open FUP is needed here. If the Patient doesn't need to answer the STIGMA questionnaire 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)

Nested Studies

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

5.7) Manage Events and Checking Charts

Manage events

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.

The screenshot shows a dropdown menu titled 'Manage events'. The menu items are: Hospitalization, Disease, Clinical Event, SNOI, STD, Fibroscan, Biopsy, Resistance, DEXA, and FRAX. The 'Clinical Event' and 'Disease' items are circled in red. A red arrow points from the 'Clinical Event' circle to the text on the right.

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.

The screenshot shows a notification titled 'Checking chart sent'. Below the title is a grey bar with a minus sign. At the bottom of the notification is a blue button with the text 'No, Please fill out the checking chart here or on paper'. A red arrow points from this button to the text on the left.

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

The screenshot shows the 'Swiss HIV Cohort Study' interface. At the top, there is a search bar for 'Cohort patient ID' with an 'Open' button and a 'Create patient' button. Below this is a navigation bar with buttons for 'Quality checks', 'Import FIRE lab data', 'Benchmarks', 'Status', and 'Nested studies'. Underneath is a 'Follow-Ups' section with tabs for 'All', 'In Progress', 'In Review', 'Submitted', 'Finalized', and 'Open Tickets'. The 'Open Tickets' tab is highlighted in a red circle and contains a yellow badge with the number '15' and a blue badge with the number '1'. A red arrow points from the 'Open Tickets' tab to the text below.

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



A horizontal header row for a ticket list. It contains the following elements from left to right: a yellow vertical bar, the ticket ID '69999', the date '26.04.2020', the name 'Niklaus Labhardt', another name 'Kerstin Asal', a yellow warning icon with a '1' inside, a blue 'Edit' button, a green 'Finalize' button, and a dropdown arrow.

Tickets

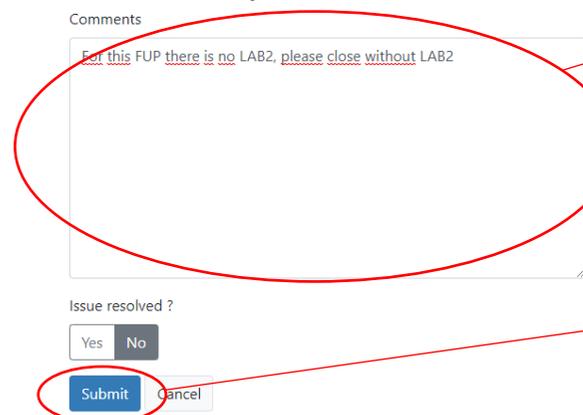
Step 2: now you see the ticket



A detailed view of a ticket. At the top, it shows the status 'Open', a calendar icon, the date and time '28.05.2021 11:12', and the user 'Jan Meier'. There are 'Edit' and 'Delete' buttons. The main content area contains the title 'missing LAB's' and the text 'There was no LAB2 due to this FUP. You can close the FUP without LAB2.'. At the bottom, there are 'Add Comment' and 'Resolve' buttons.

Step 3: Click on "Add Comment" to answer the ticket

Add follow-up ticket comment



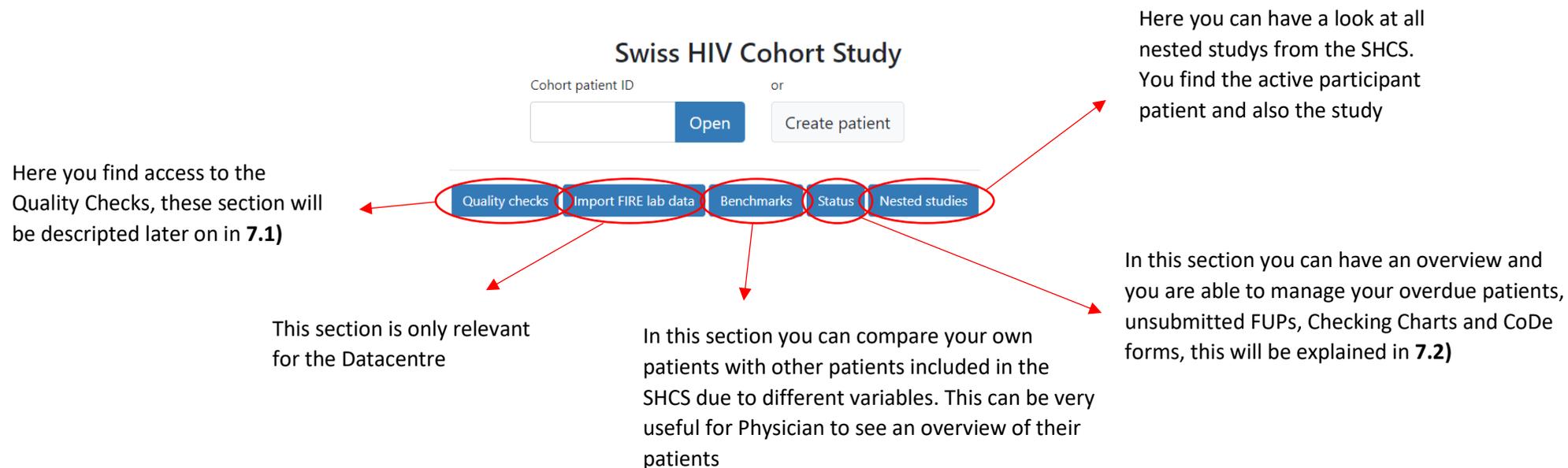
A form for adding a follow-up comment. It has a 'Comments' label and a text area containing the text 'For this FUP there is no LAB2, please close without LAB2'. Below the text area, there is a question 'Issue resolved?' with 'Yes' and 'No' radio buttons. At the bottom, there are 'Submit' and 'Cancel' buttons.

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:



7.1) Quality Checks

Quality checks

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

Failed Quality Checks

Date	Problem Description	Problem Value	Comments	Checked?
28.09.2015	patient ID currently receiving ≥ 5 ART drugs		<input type="text" value="Comments"/>	<input type="button" value="Yes"/> <input type="button" value="No"/>

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

Step2: You can check the problem description and add your 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.

Patient/Follow up status

Filter by Physician, Study

Filter

Overdue patients

Unsubmitted follow ups

Pending checking charts

Pending 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.