

secuTrial training course: SAE and PRF handling for investigators

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Table of contents

1. General information
2. Technical aspects
3. Follow-up reports
4. Critical SAE report sections
5. Training completed

1. General information: Rationale for restricted investigator access

- Serious Adverse Events (SAEs) and pregnancy reports are important safety information and must be reported to the sponsor within 24 hours of awareness. Investigator assessment and signature are required.
 - To edit and sign the electronic SAE form and Pregnancy Report Form (PRF), investigators must have access to secuTrial. However, full access requires extensive training.
- Benefits of the restricted access for you as an investigator:
 - Access to trial data
 - Prevention of late reporting due to lack of investigators with secuTrial accounts (e.g., if PI is on holiday)
 - No automatic email notifications
 - Minimal training required

1. General information

- SCI is using secuTrial (sT) as web based Electronic Data Capture (EDC) System developed by interActive Systems (iAS), Berlin
- This course is designed to give you the information required to properly handle SAE and pregnancy reporting in sT as an investigator
- Upon successful completion of this course, you are authorized to receive restricted access to sT, granting you editing rights for the SAE and PRF CRF and reading rights for the remaining areas of sT

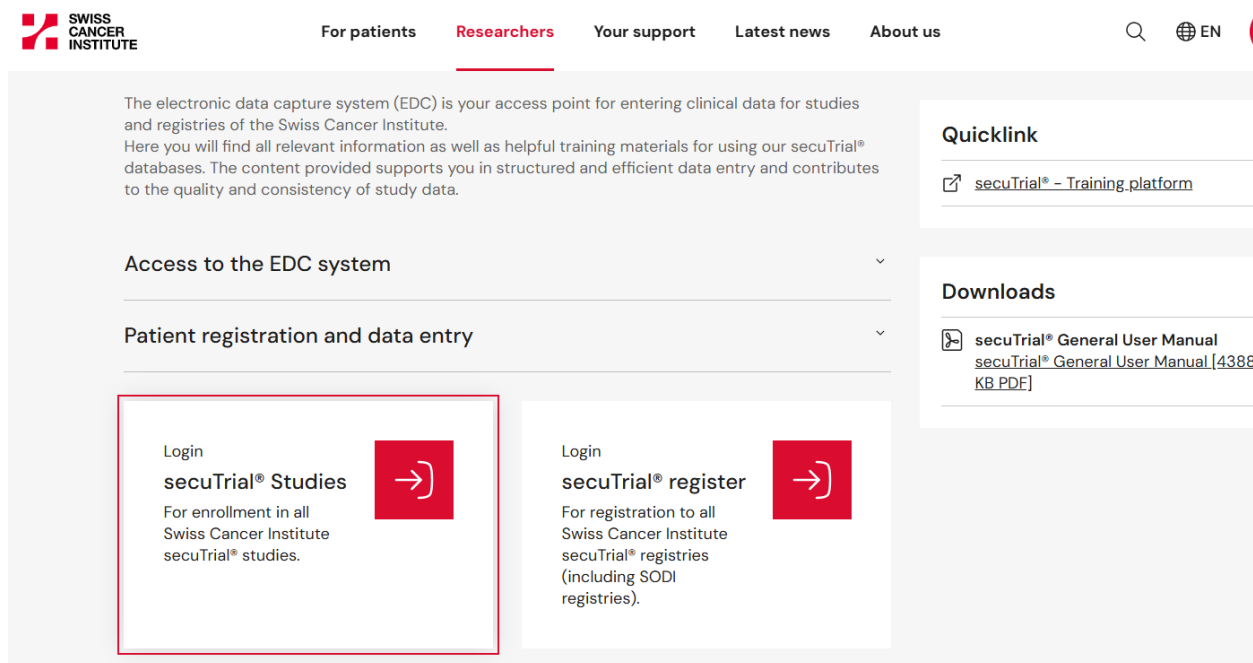
2. Technical aspects: Step-to-step guide

The following video guides you through the technical steps required for completing an SAE report in sT as an investigator:



2. Technical aspects: Further basics

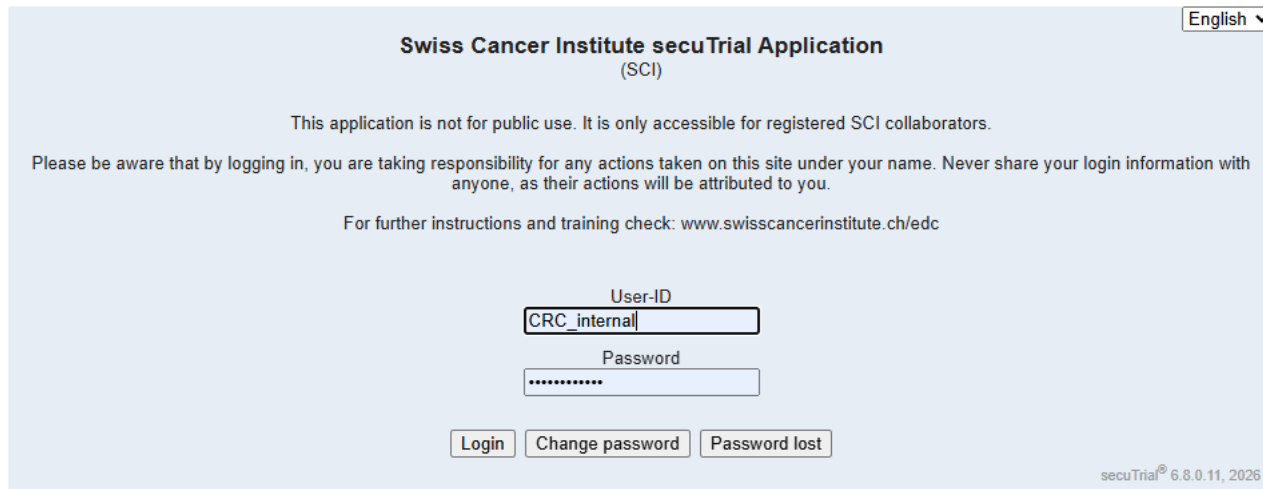
- Once the CRC has completed setting up the SAE form, you will receive an email notification with a link, leading you directly to the SAE CRF that is to be completed and signed (see video on previous slide).
- However, you can also log in to sT without this link under [Swiss EDC for Cancer Trials: Secure Data Management | Swiss Cancer Institute](#) :



2. Technical aspects: Further basics – first login

When logging in for the first time, you are asked to change your password. Your password must consist of **at least 8 characters** and a minimum of 3 of the following characters have to be used: Upper case letter, lower case letter, number, special character. Furthermore, there is a check for triviality.

Password rules can be found here



Swiss Cancer Institute secuTrial Application (SCI)

English ▾

This application is not for public use. It is only accessible for registered SCI collaborators.

Please be aware that by logging in, you are taking responsibility for any actions taken on this site under your name. Never share your login information with anyone, as their actions will be attributed to you.

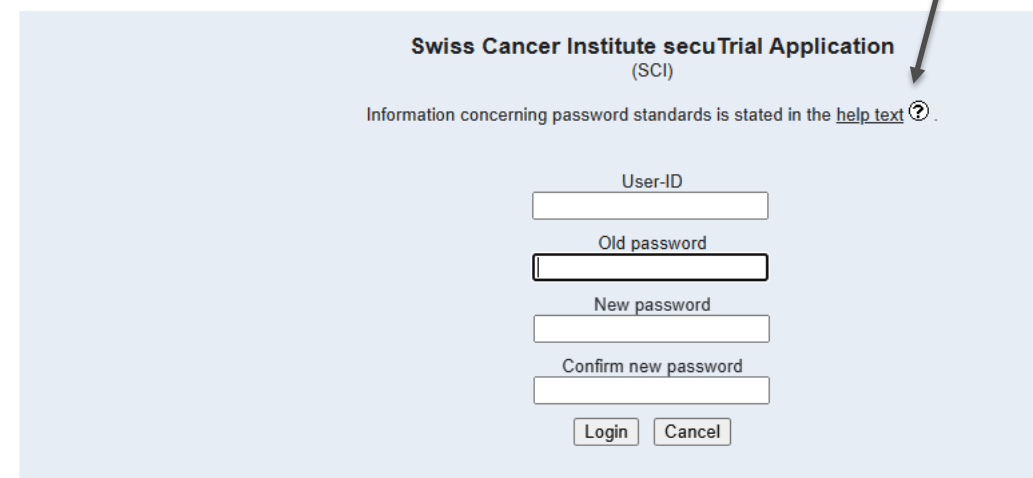
For further instructions and training check: www.swisscancerinstitute.ch/edc

User-ID
CRC_internal

Password

Login Change password Password lost

secuTrial® 6.8.0.11, 2026



Swiss Cancer Institute secuTrial Application (SCI)

Information concerning password standards is stated in the [help text ?](#)

User-ID

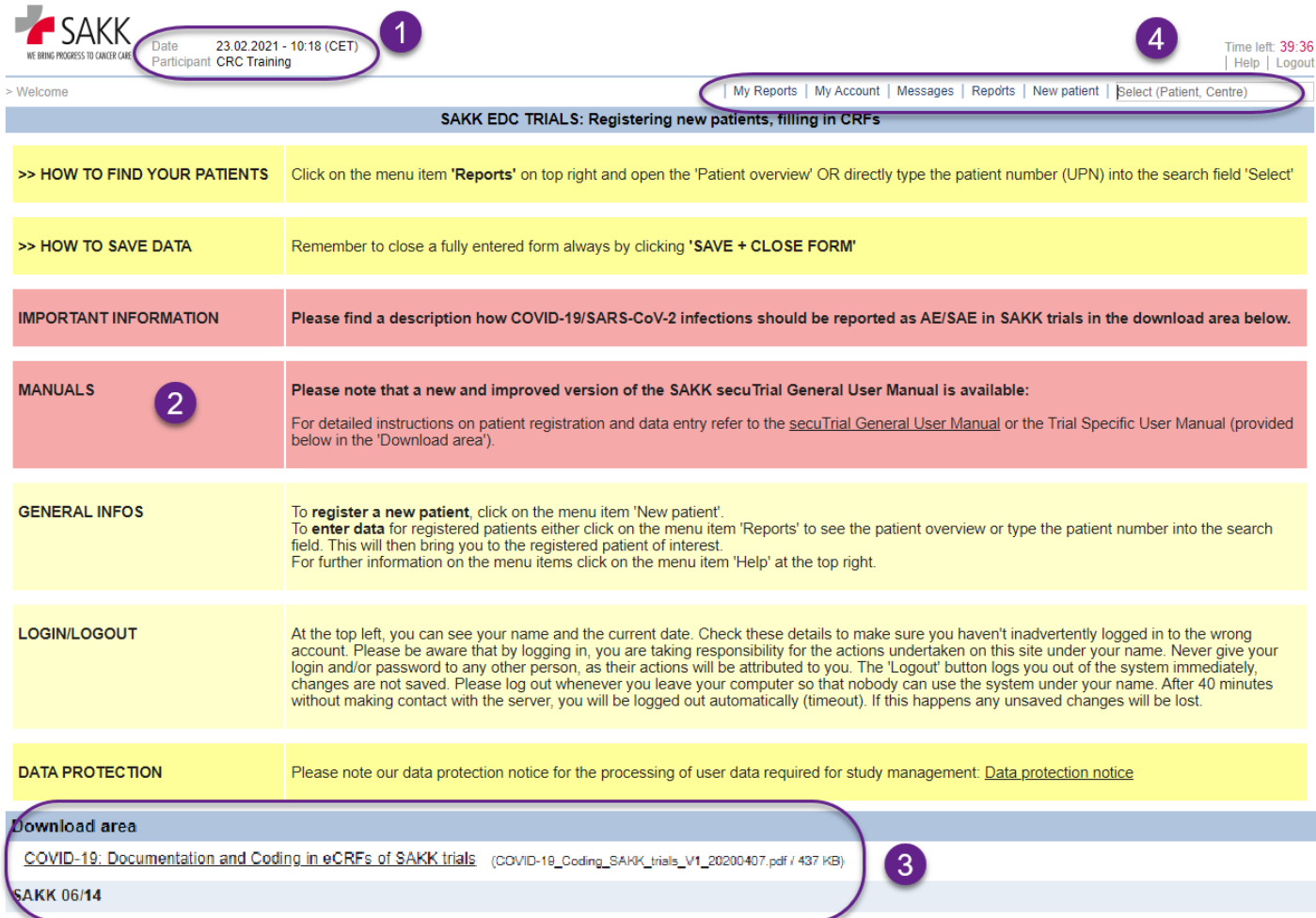
Old password

New password

Confirm new password

Login Cancel

2. Technical aspects: Further basics – Welcome Page



The screenshot shows the SAKK EDC TRIALS Welcome Page. It features a header with the SAKK logo, user information (Date: 23.02.2021 - 10:18 (CET), Participant: CRC Training), and a task bar with links like My Reports, My Account, Messages, Reports, New patient, and a search field. The main content area includes sections for finding patients, saving data, important information, manuals, general info, login/logout, and data protection. A download area at the bottom contains a link to COVID-19 documentation. Numbered annotations highlight key features: 1. User information, 2. Manuals, 3. Download area, and 4. Task bar.

SAKK
WE BRING PROGRESS TO CANCER CARE

Date: 23.02.2021 - 10:18 (CET)
Participant: CRC Training

Time left: 39:36
Help | Logout

> Welcome

SAKK EDC TRIALS: Registering new patients, filling in CRFs

>> HOW TO FIND YOUR PATIENTS Click on the menu item **'Reports'** on top right and open the 'Patient overview' OR directly type the patient number (UPN) into the search field 'Select'

>> HOW TO SAVE DATA Remember to close a fully entered form always by clicking **'SAVE + CLOSE FORM'**

IMPORTANT INFORMATION Please find a description how COVID-19/SARS-CoV-2 infections should be reported as AE/SAE in SAKK trials in the download area below.

MANUALS Please note that a new and improved version of the SAKK secuTrial General User Manual is available:
For detailed instructions on patient registration and data entry refer to the [secuTrial General User Manual](#) or the Trial Specific User Manual (provided below in the 'Download area').

GENERAL INFOS To **register a new patient**, click on the menu item 'New patient'.
To **enter data** for registered patients either click on the menu item 'Reports' to see the patient overview or type the patient number into the search field. This will then bring you to the registered patient of interest.
For further information on the menu items click on the menu item 'Help' at the top right.

LOGIN/LOGOUT At the top left, you can see your name and the current date. Check these details to make sure you haven't inadvertently logged in to the wrong account. Please be aware that by logging in, you are taking responsibility for the actions undertaken on this site under your name. Never give your login and/or password to any other person, as their actions will be attributed to you. The 'Logout' button logs you out of the system immediately, changes are not saved. Please log out whenever you leave your computer so that nobody can use the system under your name. After 40 minutes without making contact with the server, you will be logged out automatically (timeout). If this happens any unsaved changes will be lost.

DATA PROTECTION Please note our data protection notice for the processing of user data required for study management: [Data protection notice](#)

Download area
[COVID-19: Documentation and Coding in eCRFs of SAKK trials](#) (COVID-19_Coding_SAKK_trials_V1_20200407.pdf / 437 KB)

SAKK 06/14

The Welcome Page is the central place in sT

- here you start after logging in
- find the task bar to maneuver within sT
- get back there by using the **>Welcome button** on the left upper site on each page

1. User information
2. Important info e.g., **General User Manual**
3. Study specific information including Trial Specific Manual
4. Task bar

2. Technical aspects: Further basics – accessing patient's data

In order to access a specific patient, use the **Select field** and directly enter the UPN (e.g., 2316_052)

1. Study number 2316
2. Patient number 052



Date 28.05.2024 - 13:52 (CEST)
Participant Amelie Stüger

Time left: 39:53
| Help | Logout

> Welcome

My Account | Messages | Reports | Advanced search | **Select (Patient, Centre)**

SAKK secuTrial Application

>> HOW TO FIND YOUR PATIENTS	Click on the task bar item ' Reports ' on the top right-hand side and choose report ' Patient overview ' to select a patient OR use the search field to directly type in the patient number (UPN).
>> HOW TO SAVE DATA	Remember to close a fully entered form always by clicking ' SAVE + CLOSE FORM ' if available. In case of Warnings on the form, press the button a second time to save the data. In case of data modifications due to queries, add a Reason for modification next to the save button before saving the data.
MANUALS	For detailed instructions on patient registration and data entry refer to the secuTrial General User Manual or the Trial Specific User Manual (provided in the 'Download area' below). More training material and step-by-step video instructions are available on the SAKK secuTrial Training Platform .
GENERAL INFOS	To register a new patient , click the menu item 'New patient'. For further information on the menu items click on the menu item 'Help' at the top right.
LOGIN/LOGOUT	Use the Log out button to leave the application after finishing your task. After 40 minutes of inactivity, you will be logged out automatically. Data not saved at that timepoint will be lost! Do not share the log-in information with other co-workers.

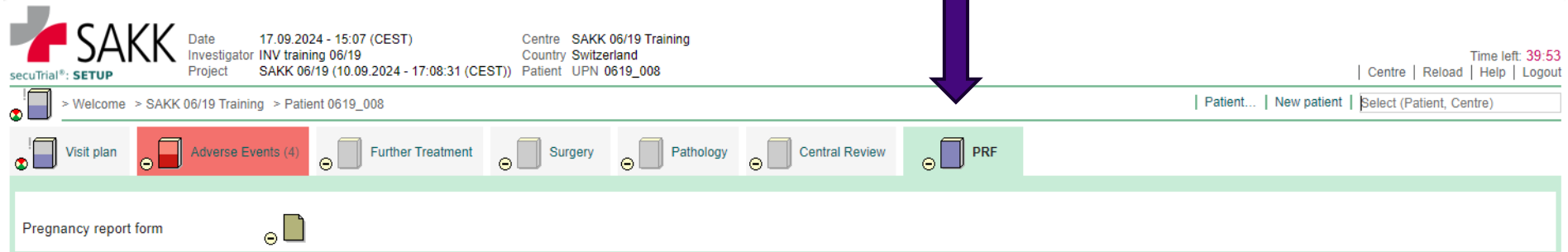
2. Technical aspects: Further basics – checks

- In sT, there are automated checks to prevent entering faulty / incomplete data
- Light red (= soft) checks can be overwritten by re-saving the form. Dark red (= hard) checks cannot be overwritten (i.e., the form cannot be saved without correction / completion of the field concerned)

2. Technical aspects: Pregnancy Report Form

The process for pregnancy reporting in sT works consistently with that of SAE reporting.

- Once the CRC has prepared the PRF, you will receive an email notification with a link taking you directly to the PRF requiring review and signature.
- Alternatively, you can access the PRF in sT:



2. Technical aspects: Pregnancy Report Form



Date 17.09.2024 - 15:02 (CEST)
 Investigator INV training 06/19
 Project SAKK 06/19 (10.09.2024 - 17:08:31 (CEST))
 Centre SAKK 06/19 Training, Switzerland

Patient UPN 0619_008
 Form family PRF
 Form Pregnancy report form

Time left: 38:57
[Back](#) | [Reload](#) | [Help](#) | [Logout](#)

[Welcome](#) > [Patient 0619_008](#) > [Pregnancy report form](#)

[SDV History](#) | [Audit Trail](#) | [Print](#)

PRF PREGNANCY REPORT FORM Document-No. 2661 - 1

FOR FEMALE PARTNERS OF MALE TRIAL PARTICIPANTS

Did the female partner give consent for the pregnancy surveillance? Deviation
☒ Yes ☐ No

Date of consent
 17 09 2024 dd.mm.yyyy

PREGNANCY DATES

Pregnancy detected on Deviation
 01 09 2024 dd.mm.yyyy

Gestational week the pregnancy was detected on
 8

Estimated delivery date
 08 04 2025 dd.mm.yyyy

PREGNANCY STATUS

Report details 1

Date of report Deviation
 17 09 2024 dd.mm.yyyy

Is the pregnancy ongoing?
☒ Yes ☐ No

[Delete](#)
[More](#)

SPECIFICATIONS AND FURTHER DETAILS

Include a description of the protocol therapy the patient received

No. 1 Deviation
 First cycle of VPM1002BC + atezolizumab on 01.09.2024

[More](#)

Last signed by CRC training 06/19
 at 17.09.2024 - 14:58:28 (CEST)
 Project version (10.09.2024 - 17:08:31 (CEST))

Validity Not signed
 Signature meaning Data edited

Language English

[Cancel](#) [Save](#) [Sign + save + close entry](#)

In order to report a pregnancy, click «Sign + save + close entry» after reviewing / editing the form.

2. Technical aspects: Where to find help

- Training can be found online: [secuTrial® Training Platform | Swiss Cancer Institute](#)
- A General User Manual (GUM), which covers all technical aspects of sT in detail, can be found on the Login Page as well as on the Welcome Page
- A Trial Specific Manual which covers the data entry guidelines for a study can be found on the Welcome Page
- In case of questions concerning SAE entry, please contact safety@swisscancerinstitute.ch

3. Follow-up reports

- After investigator signature, the SAE report will be locked for editing (i.e., no further changes can be made)
 - Exception: SCl Safety Office can re-open the report to allow for minor administrative corrections
- A follow-up report must be entered in sT **within 14 days** after initial report or as soon as the event has a final outcome (resolved / resolved with sequelae / death of the patient)
 - Data of the previous report will be automatically transferred
 - Changes from the previous report are highlighted with red boxes
 - Follow-up reports must also be signed by an authorized investigator -> SCl only receives notice of a follow-up report once it has been signed
 - With every follow-up report, please remember to check if any term / grade / causality assessment update is needed to incorporate new medical findings
- If necessary, SCl Safety Office will send out queries via email. In most cases, these can be answered when entering the follow-up report.

4. Critical SAE report sections

Please pay special attention to the following critical sections of the SAE report, concerning medical content:

- **Term:** Ensure that the term chosen is the most appropriate term according to CTCAE catalogue. The term should reflect the main diagnosis used to describe the event (whenever possible, a description of symptoms should be replaced by the underlying cause in the course of the event).
- **Causality assessment:** Please assess causality for all listed treatments and remember to update causality assessment according to new medical findings.
- **Investigator's opinion:** This section is mandatory for events that were assessed as unlikely related or unrelated to trial treatment. Please provide the rationale for your causality assessment and underlying causes.

5. Training completed: What now?

- Document the training in a training log
- Check if the staff list is completed accordingly (Add responsibility “4. Signing and reporting of Serious Adverse Events and Pregnancies”):
 - Please send a copy of the training log and the updated staff list (if applicable) to the responsible SCI CRA.
- Data management (DM) will send within 2 business days 2 emails to your attention with the following content:
 - Your SCI secuTrial **user ID**
 - Your SCI secuTrial **password**
- Now you can log in under [Swiss EDC for Cancer Trials: Secure Data Management | Swiss Cancer Institute](#).

5. Training completed: Important notes

- One login for all your SCI trials
- You will only have access to patients registered at your site
- In order to obtain editing rights for the other sT CRFs (outside of SAE and PRF), further training is required
- In case you forgot your password: Do not keep trying to enter a password that is not accepted!
 - After 4 failed attempts your account will be inactivated and you have to contact the responsible CPM/CRA
 - Instead, use the “Password Lost” button to request a new one
- Please log out after each session to ensure forms stay editable and to prevent unauthorized access

Thank you for your
help in safety
reporting, it is of great
value!

Data quality

Patient safety

