

secuTrial training course: eSAE handling for investigators

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We want the best possible cancer therapy.

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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 (eSAE) 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



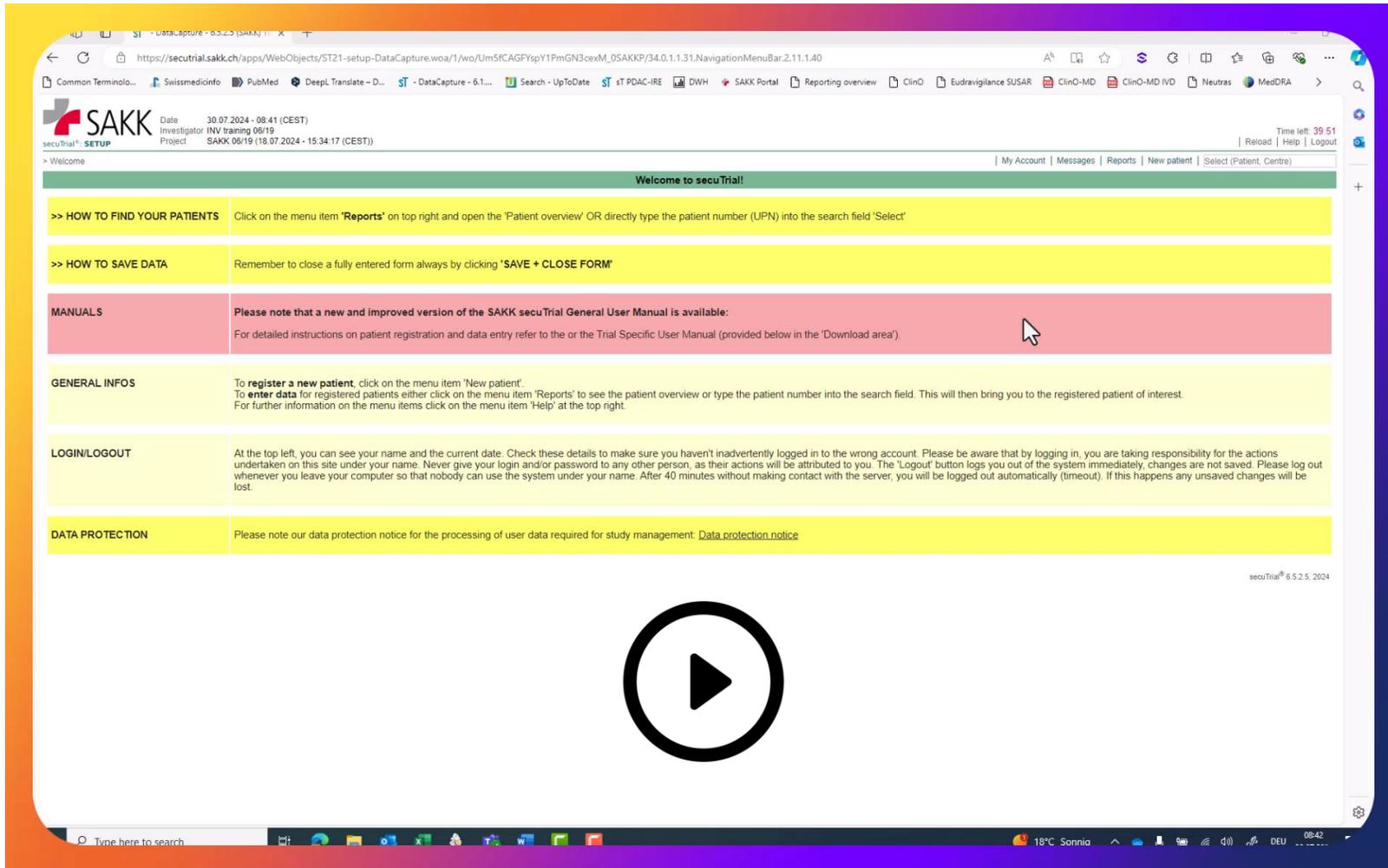
1. General information

- SAKK 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 eSAE 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 eSAE report in sT as an investigator:



The screenshot shows the SAKK secuTrial SETUP page. The browser address bar displays the URL: https://secutrial.sakk.ch/apps/WebObjects/ST21-setup-DataCapture.woa/1/wo/Um5fCAGFYspY1PmGN3cesM_0SAKKP/34.0.1.1.31.NavigationMenuBar.2.11.1.40. The page header includes the SAKK logo and the following information: Date: 30.07.2024 - 08:41 (CEST), Investigator: INV training 06/19, Project: SAKK 06/19 (18.07.2024 - 15:34:17 (CEST)). The time left is 39:51. Navigation links include My Account, Messages, Reports, New patient, and Select (Patient, Centre). The main content area is a table with the following sections:

>> 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"
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 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

The page footer includes the text "secuTrial® 6.5.2.5. 2024". A large play button icon is overlaid on the bottom half of the screenshot, indicating a video player.



2. Technical aspects: Further basics

- Once the CRC has completed setting up the eSAE form, you will receive an email notification with a link, leading you directly to the eSAE 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 <http://www.sakk.ch/edc>:

The screenshot shows the SAKK website interface. At the top, there is a red navigation bar with links for 'For patients', 'For researchers', 'About us', and 'Network'. A search bar is located on the right side of this bar. Below the navigation bar, the main content area is divided into two columns. The left column contains a vertical menu with links for 'Trials', 'Events', 'News', and 'Portal'. The right column is titled 'Electronic Data Capture (EDC)' and contains the following text: 'Please click on the icon of the appropriate EDC system for your trial if you would like to register a new patient or enter/edit data of an already registered patient. You will then be forwarded to the login page of the respective EDC system.' Below this text, there are three sections, each with a heading and a description: 'For login to all SAKK secuTrial trials click on the icon below:' followed by the 'secuTrial' logo (circled in red), 'For login to all SAKK secuTrial registries click on the icon below:' followed by the 'secuTrial Registry' logo, and 'For login to all SAKK Sinatras trials click on the icon below:' followed by the 'Sinatras' logo. A small 'CO' logo is visible in the bottom left corner of the page.



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

SAKK EDC TRIALS: Registering new patients, filling in CRFs
(SAKK)

This area is not for public viewing. It is only accessible to registered SAKK members. If you are a registered user, please enter your user-ID and password in the respective fields. When you login for the first time, you will be required to change your password. At subsequent logins, the password can be changed manually by using the button 'Change password'.

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.

For news check: www.sakk.ch

1

User-ID

Password

SAKK EDC TRIALS: Registering new patients, filling in CRFs

Information concerning password standards is stated in the help text (question mark icon)

2

Please change your password.

Password rules can be found here

User-ID

Old password

New password

Confirm new password



2. Technical aspects: Further basics – Welcome Page

The screenshot shows the SAKK EDC TRIALS Welcome Page. At the top left is the SAKK logo with the tagline 'WE BRING PROGRESS TO CANCER CARE'. To its right, a box contains the date '23.02.2021 - 10:18 (CET)' and 'Participant: CRC Training', with a circled '1' next to it. Further right is a task bar with links: 'My Reports', 'My Account', 'Messages', 'Reports', 'New patient', and 'Select (Patient, Centre)', with a circled '4' next to it. The main content area is a table with several rows: 'HOW TO FIND YOUR PATIENTS', 'HOW TO SAVE DATA', 'IMPORTANT INFORMATION', 'MANUALS', 'GENERAL INFOS', 'LOGIN/LOGOUT', and 'DATA PROTECTION'. The 'MANUALS' row has a circled '2' next to it. At the bottom, there is a 'Download area' section with a link to 'COVID-19: Documentation and Coding in eCRFs of SAKK trials' and a circled '3' next to it. The page footer shows 'SAKK 06/14' and a 'Time left: 39:36' indicator.

Category	Content
>> 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

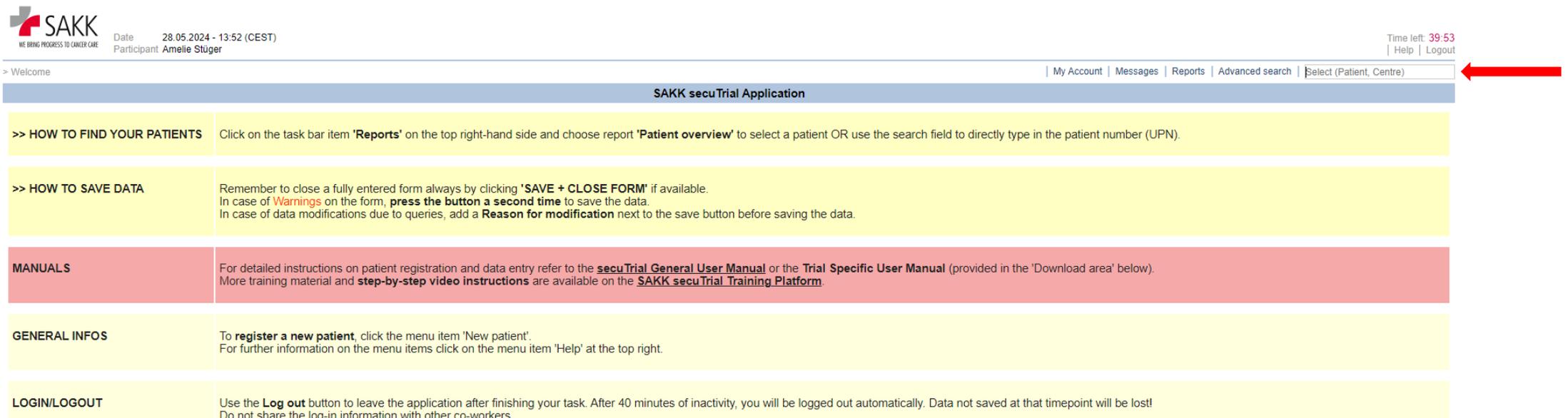
1. User information
2. Important info e.g., **General User Manual**
3. Study specific information including Trial Specific Manual
4. Task bar



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



SAKK WE BRING PROGRESS TO CANCER CARE 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

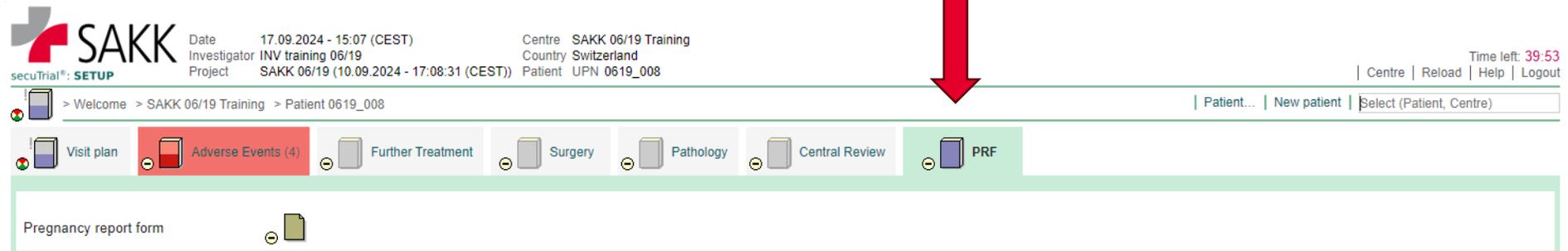
- In sT, there are automated checks to prevent entering faulty / incomplete data
- **Light red (= soft)** checks can be overwritten by re-saving the form. **Dark red (= hard)** checks cannot be overwritten (i.e., the form cannot be saved without correction / completion of the field concerned)



2. Technical aspects: Pregnancy Report Form

The process for pregnancy reporting in sT works consistently with that of eSAE 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:



The screenshot displays the SAKK secuTrial interface. At the top left is the SAKK logo. The header contains the following information: Date: 17.09.2024 - 15:07 (CEST), Investigator: INV training 06/19, Project: SAKK 06/19 (10.09.2024 - 17:08:31 (CEST)), Centre: SAKK 06/19 Training, Country: Switzerland, Patient: UPN 0619_008. On the right, it shows 'Time left: 39:53' and navigation links: Centre | Reload | Help | Logout. Below the header is a breadcrumb trail: > Welcome > SAKK 06/19 Training > Patient 0619_008. A navigation bar contains icons for Visit plan, Adverse Events (4), Further Treatment, Surgery, Pathology, Central Review, and PRF. The PRF icon is highlighted in green. Below the navigation bar, the PRF section is visible, showing 'Pregnancy report form' with a document icon. A large red arrow points from the top of the page down to the PRF icon in the navigation bar.



2. Technical aspects: Pregnancy Report Form

 Date 17.09.2024 - 15:02 (CEST) Patient UPN 0619_008
Investigator INV training 06/19 Form family PRF
Project SAKK 06/19 (10.09.2024 - 17:08:31 (CEST)) Form Pregnancy report form
Centre SAKK 06/19 Training, Switzerland

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? Yes No Date of consent 17-09-2024 dd.mm.yyyy

PREGNANCY DATES

Pregnancy detected on 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 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 First cycle of VPM1002BC + atezolizumab on 01.09.2024

Delete 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 Signature meaning Not signed Data edited Language English

Cancel Save **Sign + save + close entry**

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 Country: Switzerland
UPN: 0619_008 Form family: PRF Form: Pregnancy report form Document-No. 2661 - 1

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: [SAKK secuTrial Trainings Platform](#)
- 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 eSAE entry, please contact safety@sakk.ch



3. Follow-up reports

- After investigator signature, the eSAE report will be locked for editing (i.e., no further changes can be made)
 - Exception: SAKK 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 -> SAKK 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, SAKK Safety Office will send out queries via email. In most cases, these can be answered when entering the follow-up report



4. Critical eSAE sections

Please pay special attention to the following critical sections of the eSAE 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?

- This training should be documented in the training log and the staff list completed accordingly:
 - Please send a copy of the training log and the updated staff list (if applicable) to the responsible SAKK CRA.
- Data management (DM) will send within 2 business days 2 emails to your attention with the following content:
 - Your SAKK secuTrial **user ID**
 - Your SAKK secuTrial **password**
- Now you can log in under <http://www.sakk.ch/edc>.



5. Training completed: Important notes

- One login for all your SAKK 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 eSAE 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!

Patient
safety

Data quality

We want the best possible cancer therapy.