secuTrial training course: eSAE handling for investigators

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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

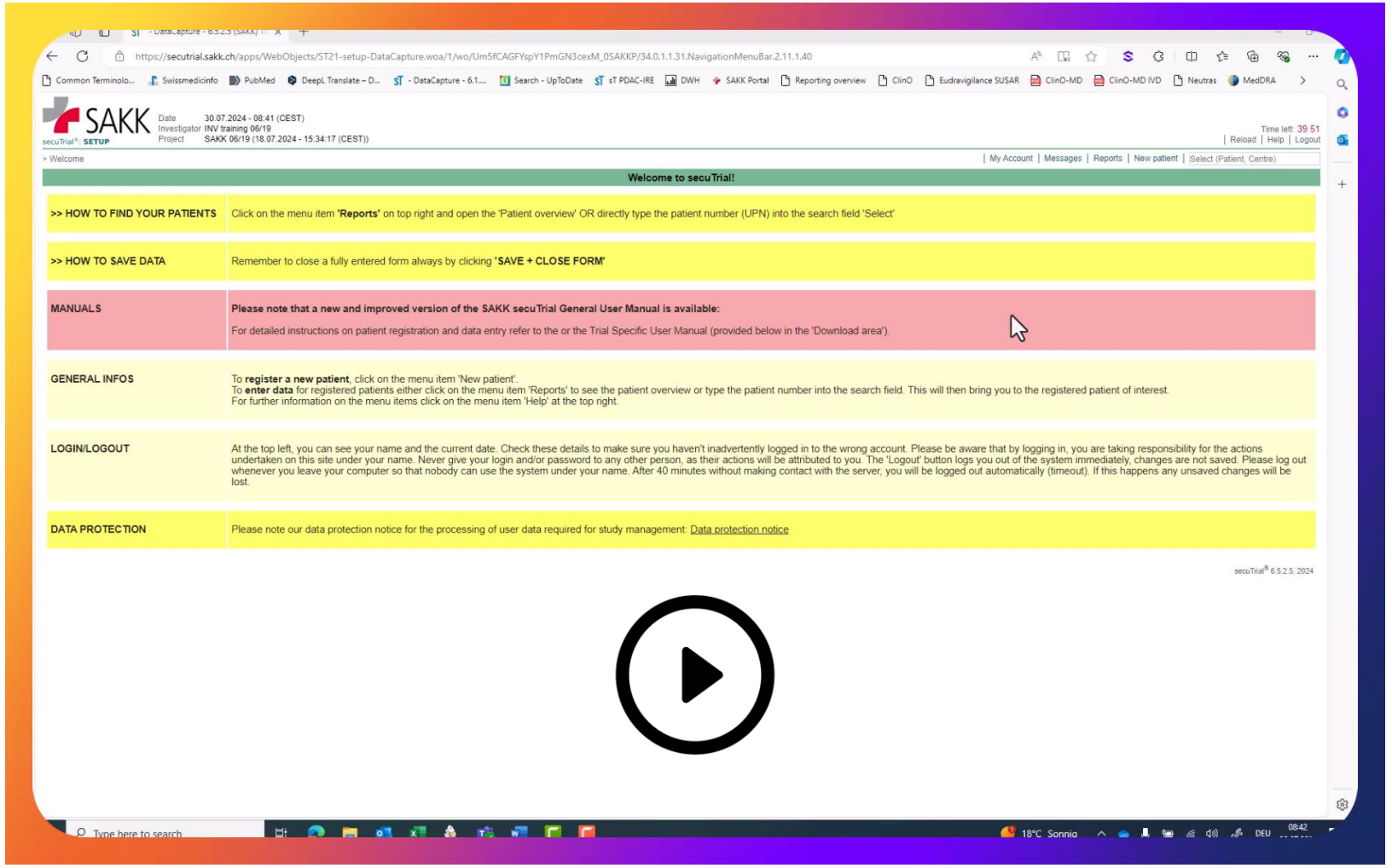
- SAKK is using secuTrial (sT) as web based Electronic Data Capture (EDC) System developed by interActive Systems (iAS), Berlin

- 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

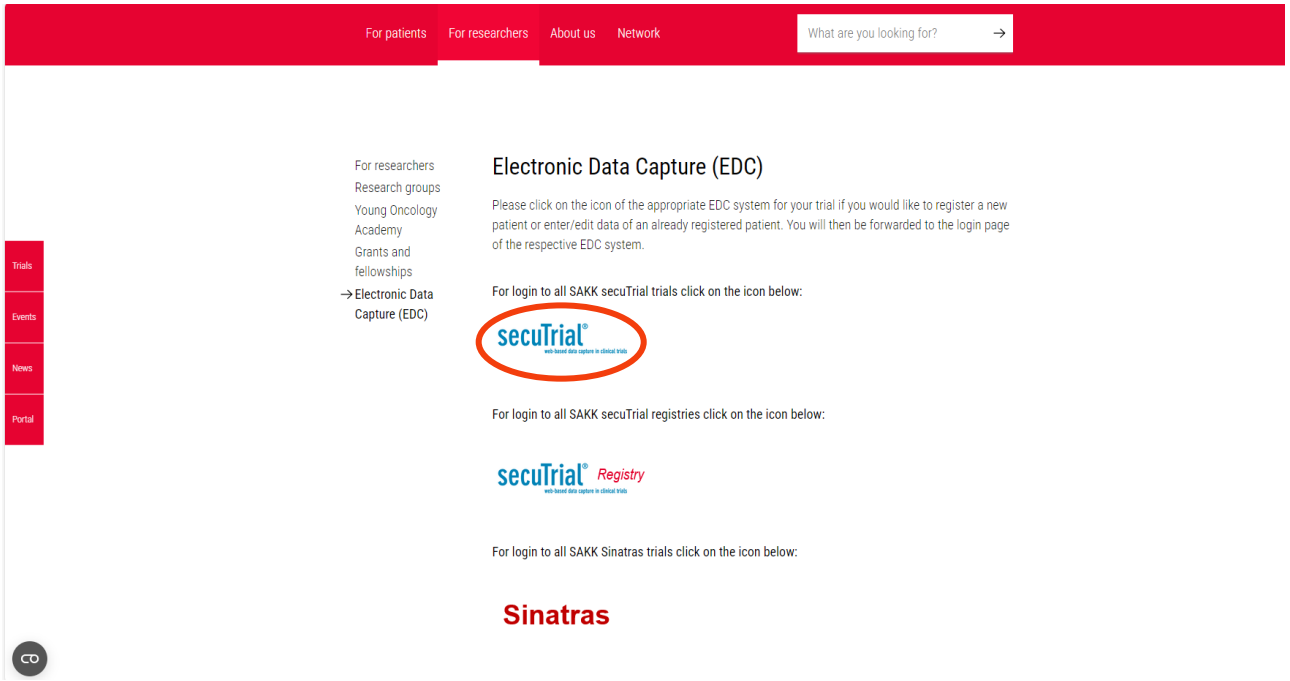
The following video guides you through the technical steps required for completing an eSAE report in sT as an investigator:



2. Technical aspects: Further basics

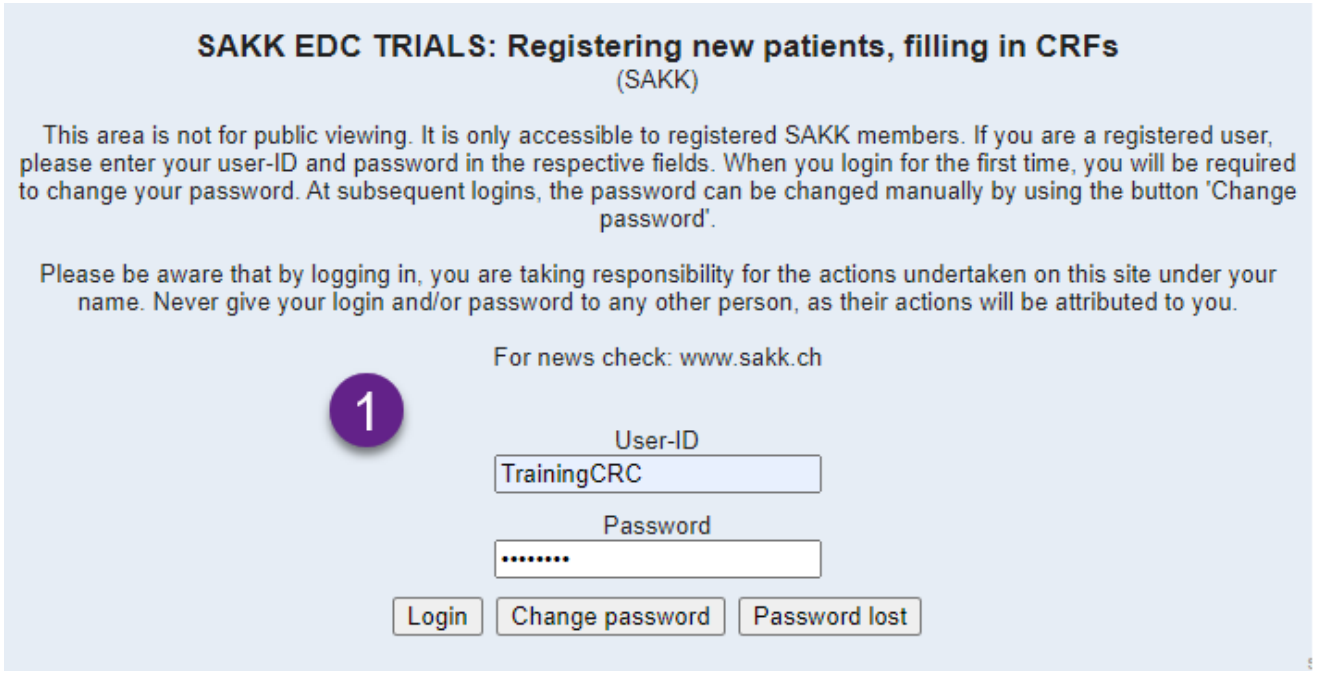
- Once the CRC has completed setting up the eSAE form, you will receive an email notification with a link, leading you directly to the eSAE CRF that is to be completed and signed (see video on previous slide).

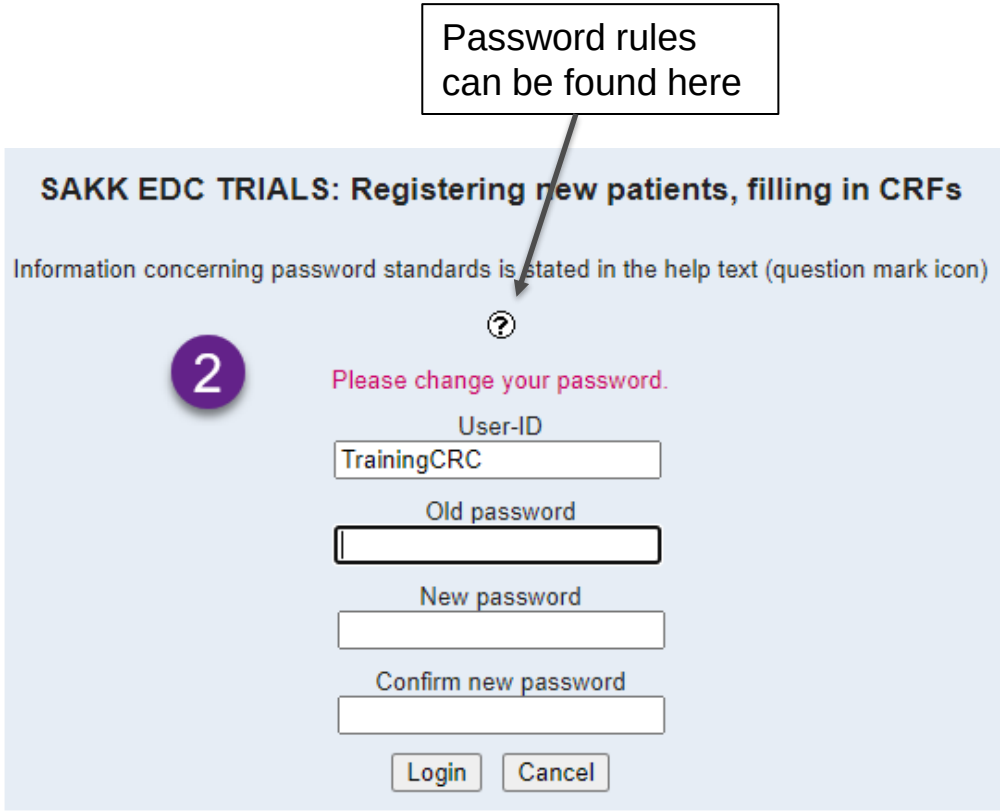
- However, you can also log in to sT without this link under http://www.sakk.ch/edc:



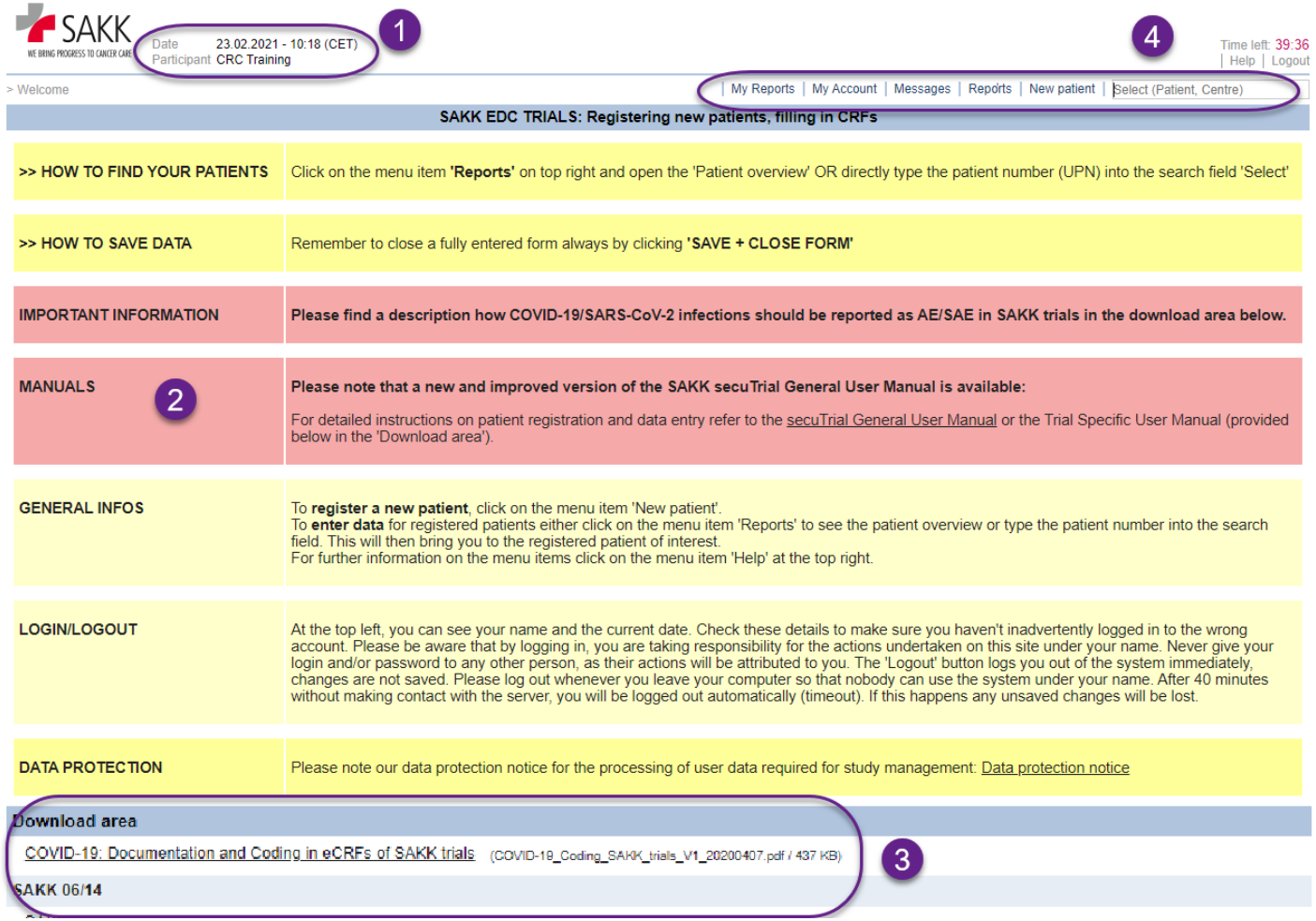
2. Technical aspects: Further basics – first login

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.





2. Technical aspects: Further basics – Welcome Page



The Welcome Page is the central place in sT

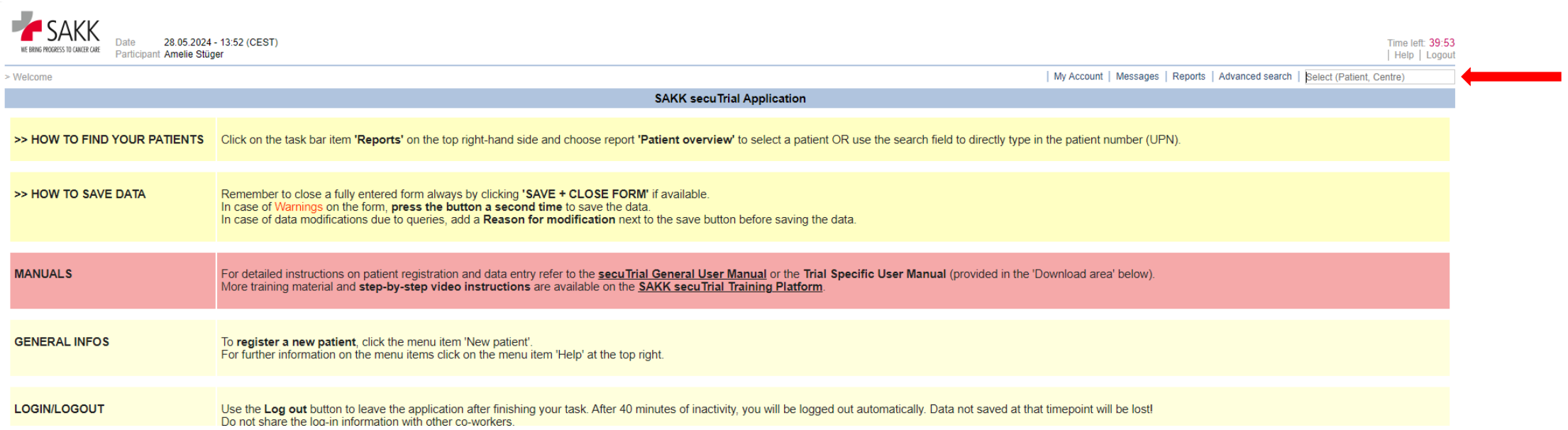
- here you start after logging in
- find the task bar to maneuver within sT
- get back there by using the >**Welcome button** on the left upper site on each page

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



2. Technical aspects: Further basics – checks

- In sT, there are automated checks to prevent entering faulty / incomplete data

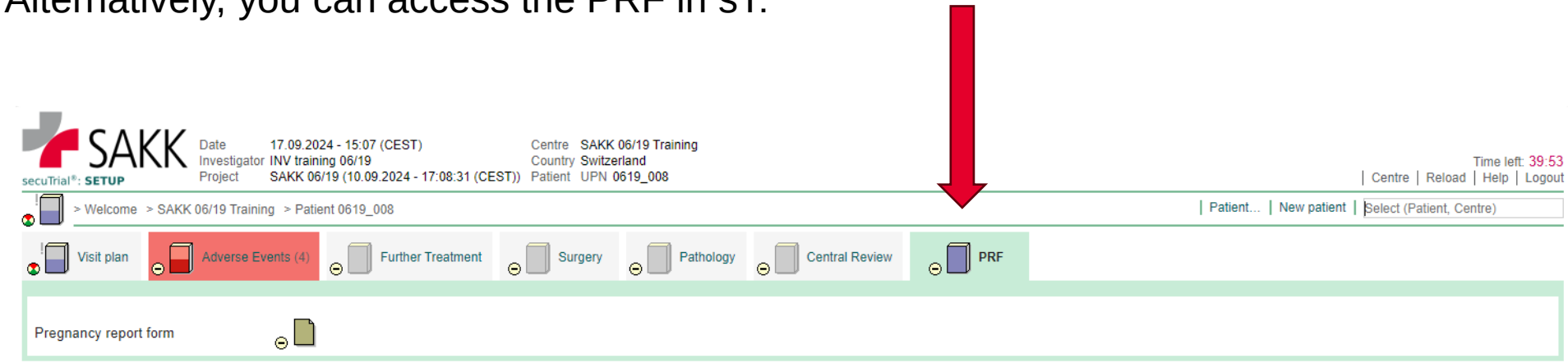
- Light red (= soft) checks can be overwritten by re-saving the form. Dark red (= hard) checks cannot be overwritten (i.e., the form cannot be saved without correction / completion of the field concerned)

2. Technical aspects: Pregnancy Report Form

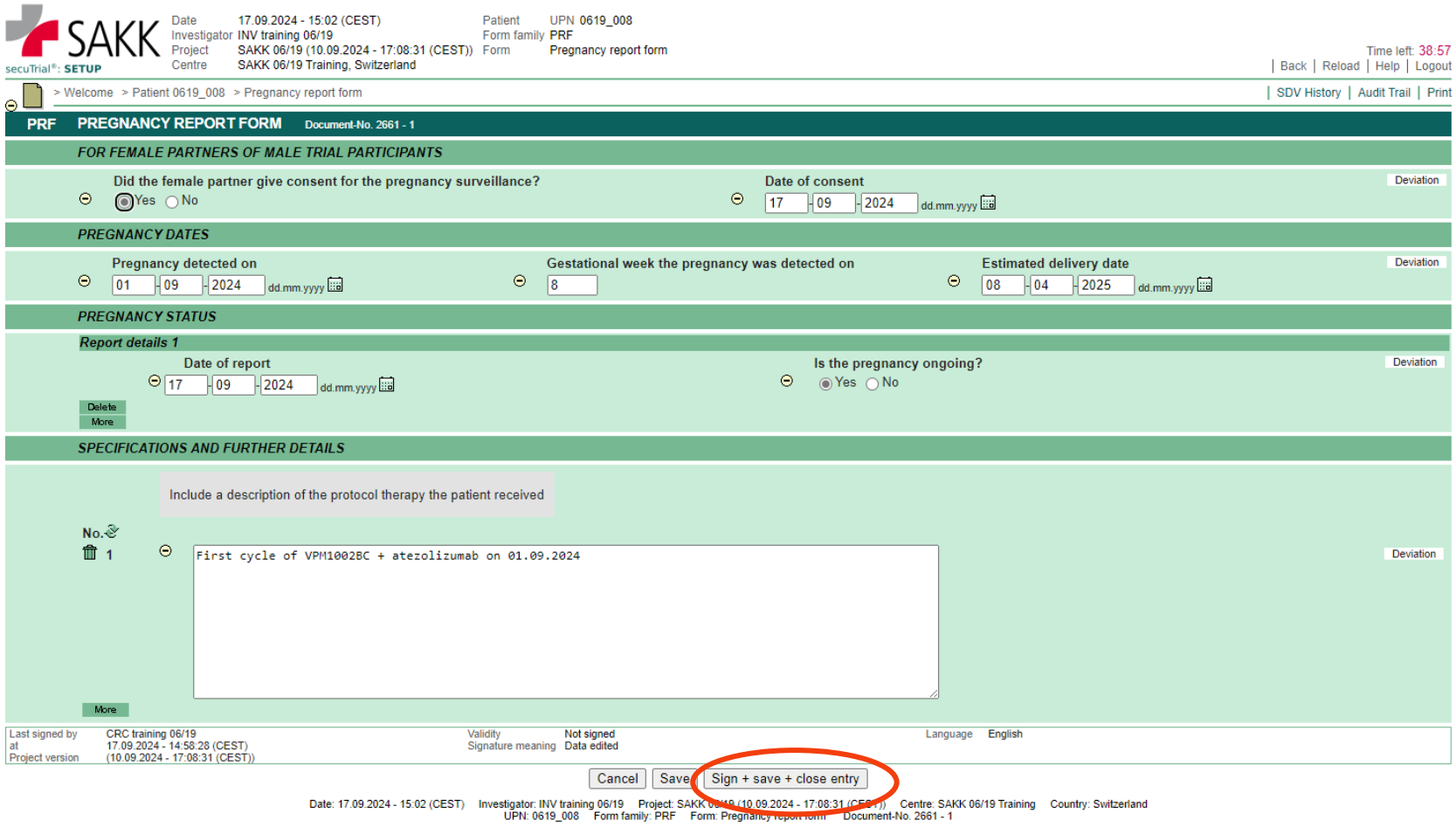
The process for pregnancy reporting in sT works consistently with that of eSAE reporting.

- 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:



2. Technical aspects: Pregnancy Report Form



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!

Data quality

Patient safety

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