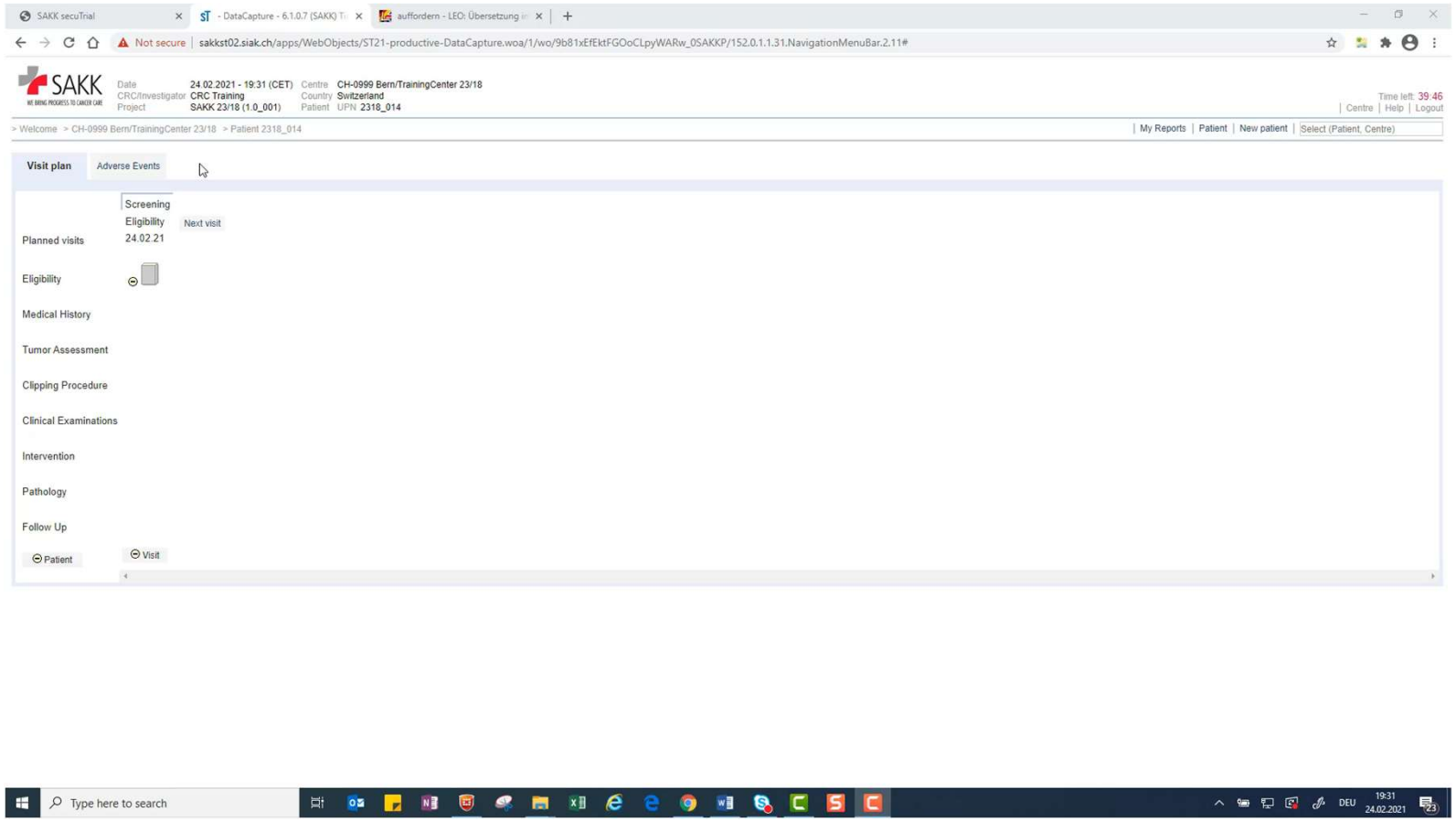
9. Data Entry – Registration forms (current version)

- Data Entry starts with the registration forms. Highly secured forms as they are used to document eligibility and inclusion of a patient.
- Prior completing the eCRF registration forms an Eligibility Worksheet available on portal.sakk.ch has to be completed and signed by the treating investigator. *(See trial protocol section 7 for details)*
- Registration forms have to be completed entirely and correctly as well as in the correct order!

  Current registration files (from 2020 on) consists of 2 forms:
  EV Eligibility evaluations
  ER Patient registration (and randomization)

- Depending on the protocol, a pre-registration might also be necessary.
- A form has to be saved and closed (DEC) before the next one can be filled in.
- After all forms are completed, saved and closed, an email will be sent to your attention, confirming the patient's registration

9a. Data Entry – Video: registration forms (current version)



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9. Data Entry - What to take away from the video

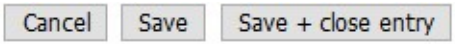
- Trying to save an eCRF form always initiates an internal data validation.
- Missing or incorrect data will trigger ‘Warnings’.
  - ‘Warnings’ can be setup as ‘Hard’- (HC) or ‘Soft’- (SC) Checks

- The existence of HC Warnings (red) on a form prevents any saving of data!
- The existence of SC Warnings (orange) on a form requires repeated saving, if new or modified data need to be saved!
- If there are no data to be saved, a form can be left using the ‘**Cancel’** button.

- If data should be saved, there are two options:
  - Using the ‘**Save’** button → only saves the data
  - Using the ‘**Save + close entry’** button → saves the data and gives the form a new status:

    Data Entry Complete (DEC) – green colored icons

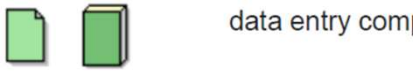
9. Data Entry Complete (DEC) - a fundamental concept in sT

- In order to save the data of a form you can click on the **'Save'** button or on **'Save + close entry'**. 

- If you enter data but you cannot complete the whole form, you can use the **'Save'** button, to revisit and finalize it later. (Only if there is no HC Warning on the form!)

- Do this only if you are sure to have the data soon. Otherwise, rather follow up as described below and reopen the form later, respectively wait for queries asking to record the missing data.

- If you have completed the form and there is no information to be added later on, you must close the data entry with the "Save + close entry" button.



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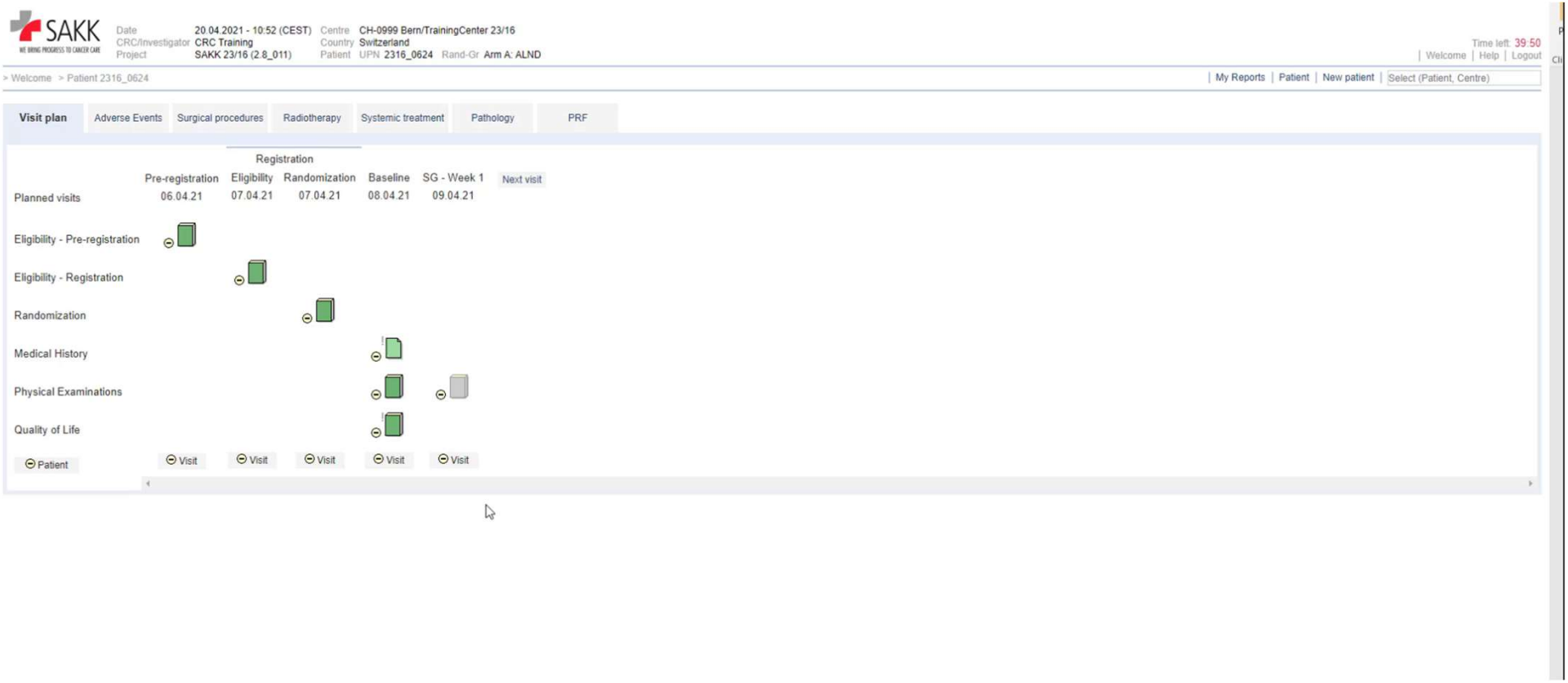
9. Data Entry Complete (DEC) - a fundamental concept in sT

- Forms closed with **'Save + close entry'** cannot be edited anymore unless you use the **'Reopen data entry'** button. 

- Closed forms are a trigger for source data verification (SDV) by the CRA or data validation by Data Management → Queries.
- As soon as one of these processes have been started, the **'Reopen data entry'** button will no longer be available.
- To modify a DEC form, ask the responsible CRA or DM to put a new Query in the section of the form you like to update. This will open only this section.

9b. Data Entry - Video: Saving data; Data Entry Complete (DEC)



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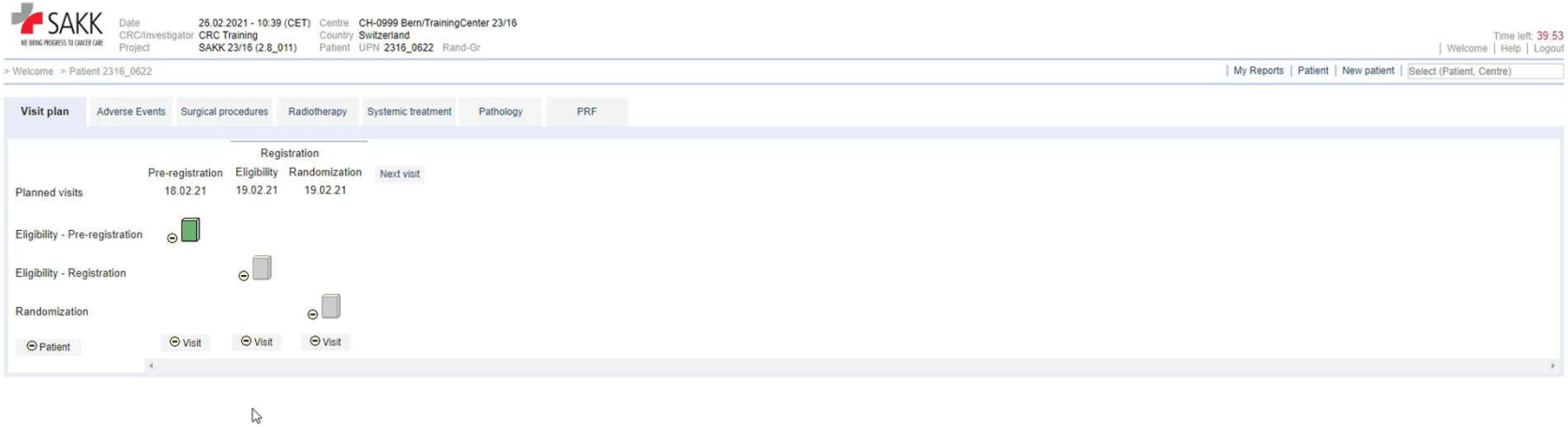
9. Data Entry - Addendum: Older Registration forms

- In older trials, we have more 3 or 4 registration forms. Plus pre-registration and randomization forms if applicable.

ER	Information on patient registration
IE	Inclusion / exclusion criteria (separate forms in very old trials)
EV	Eligibility evaluations

- The principles of completing them are similar to what we have seen previously for the latest version of the registration forms.
- The differences are:
  - the order of the forms is different. However, as long as you complete them from the left to the right you do not need to care.
  - and more important, the treating investigator has to provide his signature on the previously completed and printed **eCRF ER** form. (*See protocol section 7 for details)*

9c. Data Entry – Video: Older registration forms



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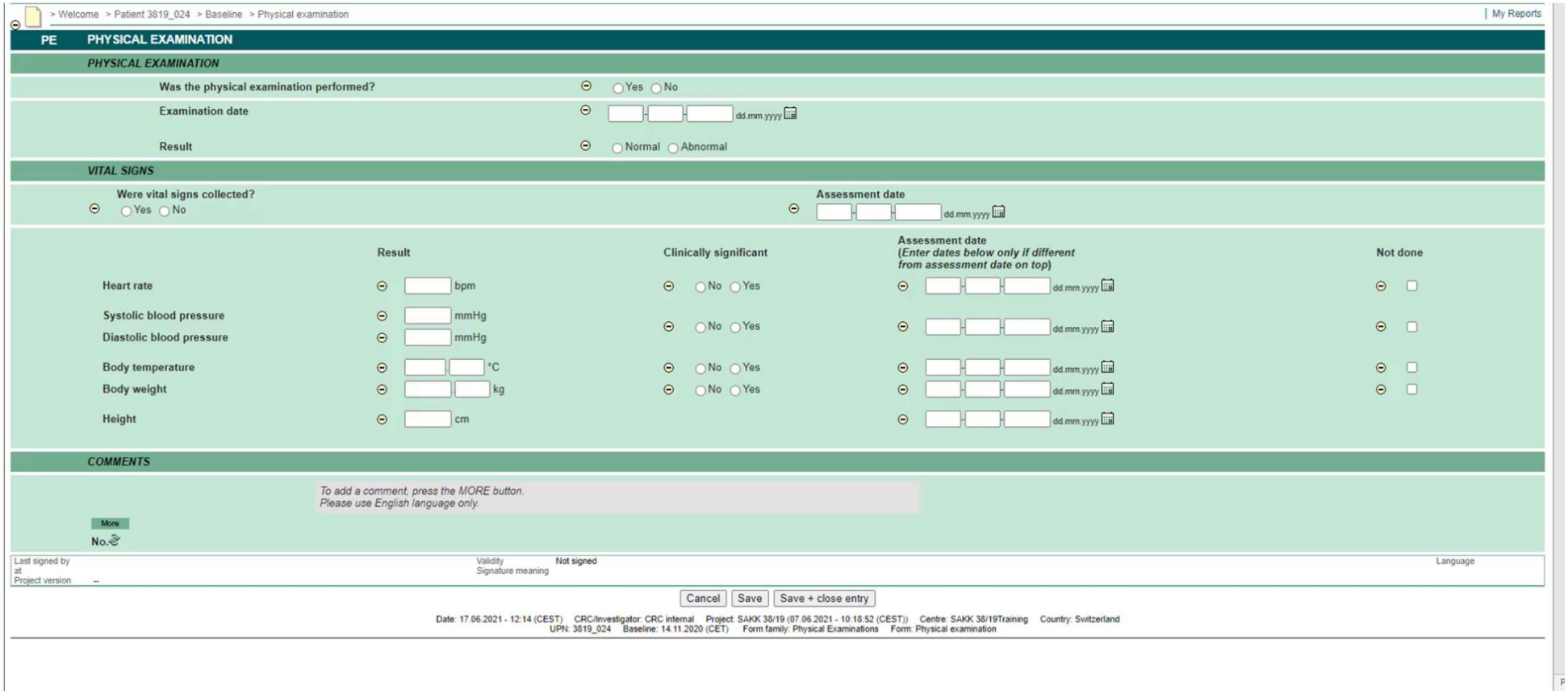
9. Data Entry - Important data entry rules

- The latest version of Data Entry rules can be found in the current version of the **General User Manual - section 7**.
- Relevant for a specific study are the instructions given in the respective **Trial Specific Manual**.

9d. Data Entry – Video: Data Entry Principles I (eCRF sections, dates, radio-button, subordinate data fields, free text fields, 'Comments' section)



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9. Data Entry – Data Entry Principles II – Repetition Groups

- To complete a flexible number of records with identical items, so called ‘Repetition Groups’ are used.
- A ‘Repetition Group’ can be identified on the eCRF by the ‘More’ button, that comes with it.
- Typical eCRFs with a ‘Repetition Group’ are Casenodes like Adverse Event or Concomitant Medication.
- Regular visit forms can come with it too, as shown in the ‘Data entry principles I’ video by presenting how to add and delete records within the ‘Comments’ section.

9. Data Entry – Data Entry Principles II – Casenodes

- Previously we learned that all forms have to be set on status Data Entry Complete (DEC) to allow CRA and DM to follow up on them.
- There is now an exception to it. The **latest generation of Casenodes**, used to document data in an ongoing manner, does **not require the DEC status** anymore and hence can be completed continuously even after SDV or Query allocation.

9e. Data Entry – Video: Data Entry Principles II – Casenodes / Repetition Groups

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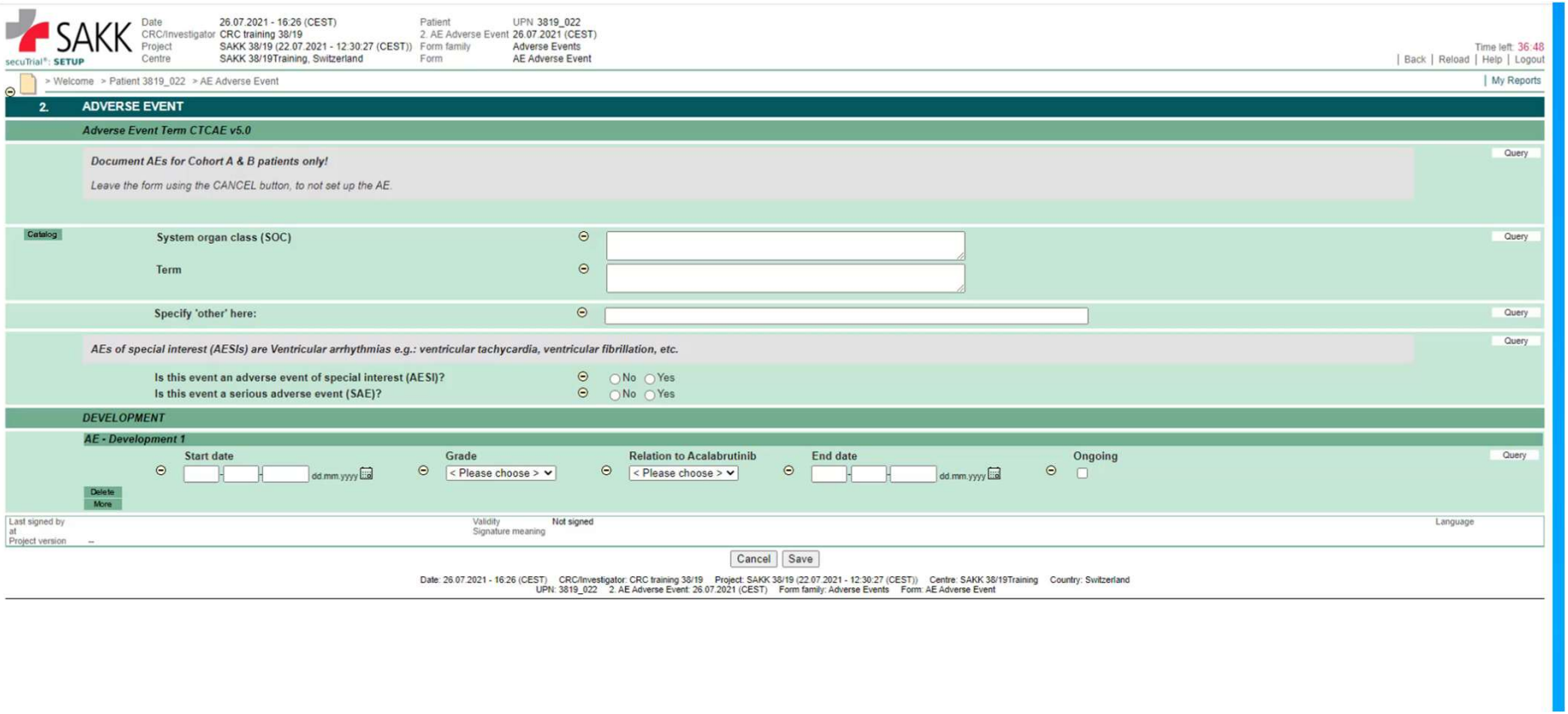
9. Data Entry – Data Entry Principles III – Catalogs

- In SAKK trials the following catalogs are used:
  - CTCAE for Adverse Events and Baseline Symptoms
  - ATC for medication

  For medication, alternatively free text fields without a catalog can be provided or dropdown menus with predefined options.

9f. Data Entry – Video: Data Entry Principles III – CTCAE



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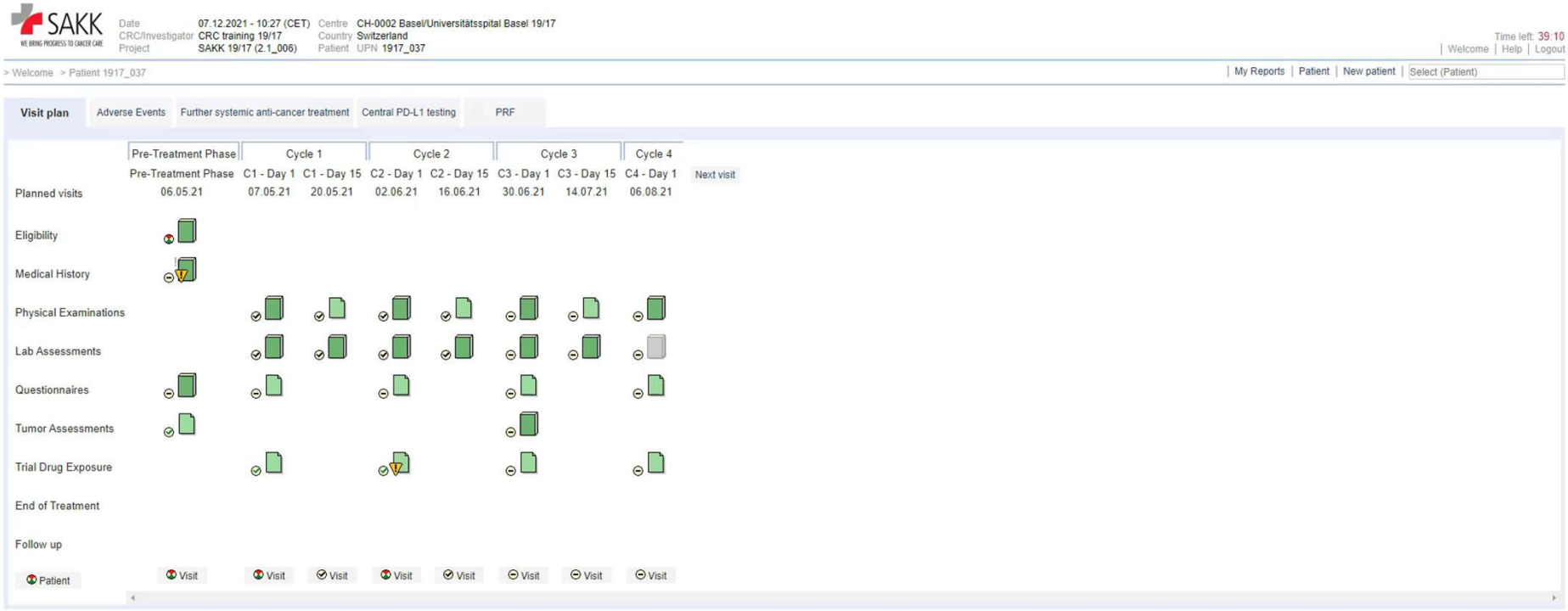
9g. Data Entry – Video: Data Entry Principles IV – document medication & ATC

Soon to come

9. Data Entry – AE and SAE

- **AEs** have to be recorded according to trial protocol chapter 10
- **SAEs** according to trial protocol chapter 11.
- For trials with a **paper based SAE reporting process**, **each SAE reported requires an AE form to be completed in addition** with equivalent data.
- For trials with **eSAE process, no such separate AE needs to be reported anymore**, as it is integrated in the eSAE form.
- AEs, which happen prior to the start of trial treatment, are considered as **Baseline Symptoms.**
- Baseline Symptoms are documented separately under the form family: Medical History.
- Baseline Symptoms, which are worsening after trial treatment start, have to be documented as AEs from the time point of worsening. (Check the protocol for possible restrictions regarding this rule).
- Always check the trial protocol and TSM for special requirements not covered above.

9h. Data Entry – Video: old AE and eSAE forms



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9i. Data Entry – Video: Latest AE and eSAE forms

Soon to come