secuTrial
General User Manual
Guideline for Site personnel

Purpose/Scope: This user manual explains the functionality of secuTrial.

It is supposed to enable site personnel to use the eCRF application to record, modify and clean clinical data as well as to use supporting reports available for each trial.

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1. Abbreviation

AE	Adverse Event
AESI	Adverse Event of Special Interest
CDM	Clinical Data Manager
CPM	Clinical Project Manager
CRA	Clinical Research Associate
CRF	Case Report Form
DEC	Data Entry Closed
DM	Data Management
eCRF	electronic Case Report Form
EDC	Electronic Data Capture
GUM	General User Manual
SAE	Serious Adverse Event
SAKK	Swiss Oncology Research Network
SAKK CC	Swiss Oncology Research Network Coordination Center
SF	Screening failure
sT	secuTrial
TSM	Trial Specific Manual
UPN	Unique Patient Number
USN	Unique Site Number

2. General notes

- Figures used to illustrate information in the following manual are taken from the sT **Setup** area (training area). This is why they appear in green instead of a blue background color, as used in the **Productive** area (area for real life data).
- The figures used are taken from several different trials and combined as needed.

3. Access to secuTrial

In order to receive authorization for online pre-registration, registration and data entry, sites have to send a copy of the completed staff list as well as the sT training log copy (for general and trial specific sT training) to the SAKK CC.

Subsequently sT login credentials (User–ID and password) will be send via email to staff member listed within 2 working days.

The responsible SAKK CPM coordinates this process and is together with the responsible CRA the person to contact.

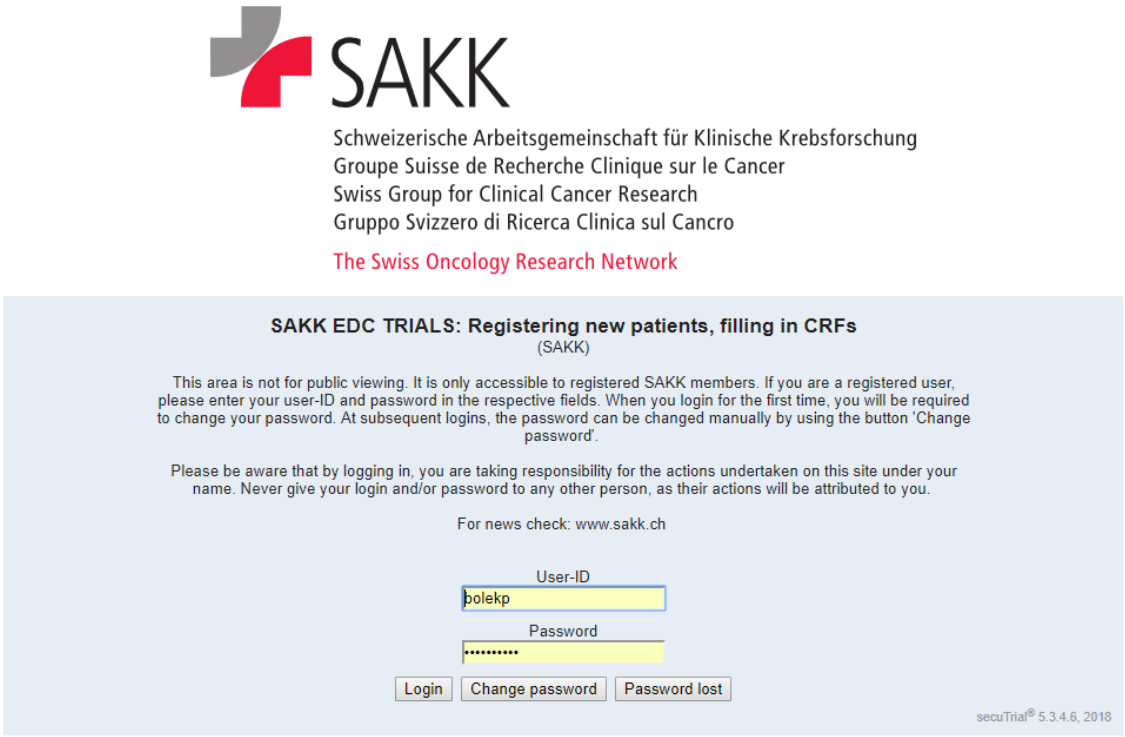
The SAKK staff list as well as the training log can be downloaded from the SAKK portal (usually to be found in the trial specific member section under Useful Tools).

Once login details are available, sT can be accessed via **www.sakk.ch/edc**

by clicking on the secuTrial icon.

!! Turn off Pop-Up Blocker when working with secuTrial !!

This will lead to the following login mask:



When logging in the first time, a password change is required.

Press button ‘Change password’ and follow the instructions.

*The password has to 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, passwords are checked concerning triviality; whereat case sensitivity is ignored. This includes examining the single characters’ sequence, not allowed are:

- *Three or more identic consecutive characters*
- *Three or more consecutive numbers being directly successive*
- *Five or more consecutive letter being directly alphabetically successive*

Context related triviality is tested as well, forbidding is the usage of IDs and names.

Moreover, passwords must not equal the last previously used passwords. In case of the new password being identic compared to the immediately previous one except for one number, this number must not be directly incremented.

If a password got lost after the first login, a new one can be requested:

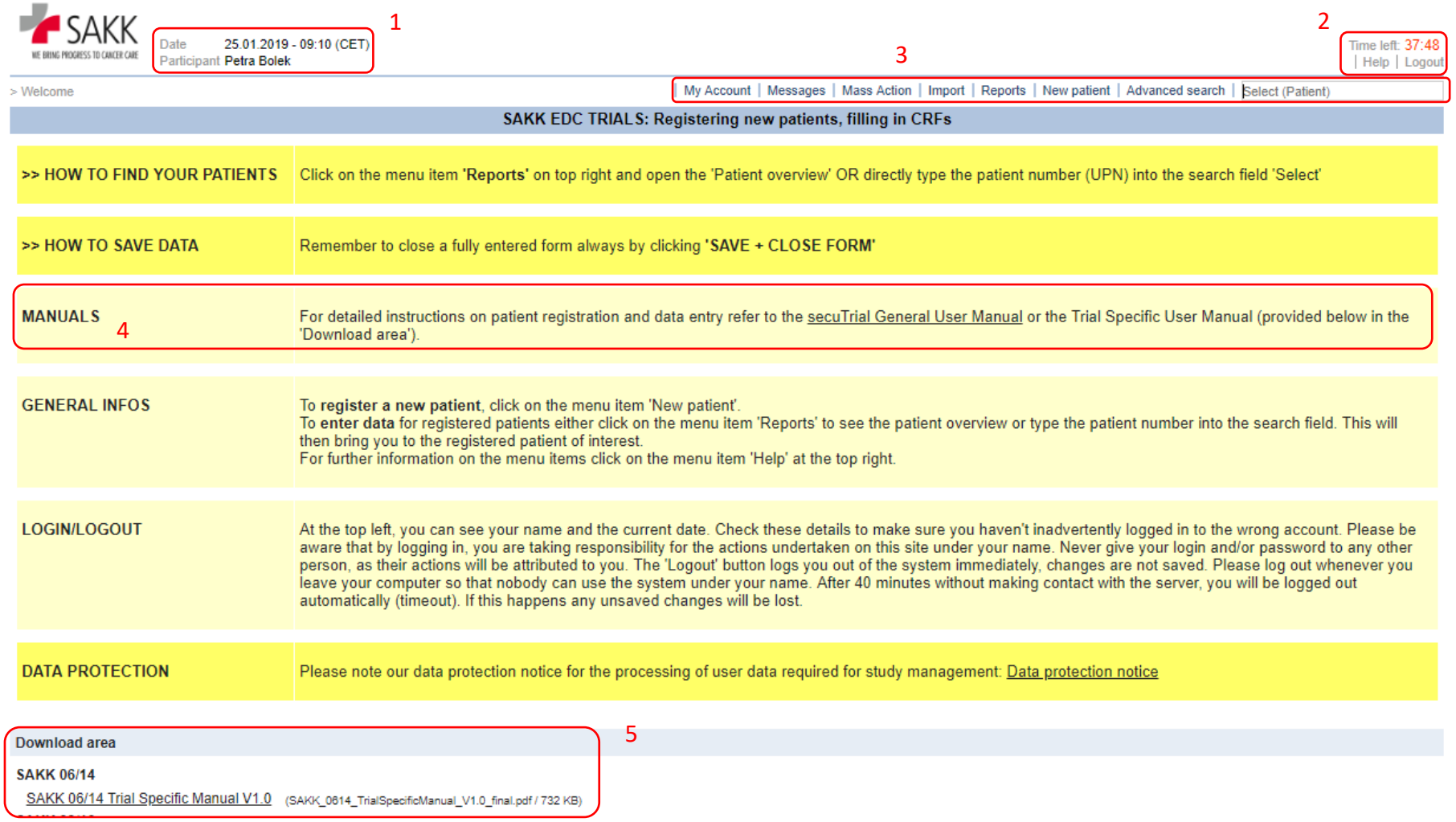
Press button ‘Password lost’ and follow the instructions.

- *A person’s login details are identical across all SAKK sT trials.*
- *The usual format of a User-ID is: last name + first letter of first name*
- *Each trial requires a separate staff list to provide staff member with access rights.*
- *Staff lists have to be kept up to date and have to be sent to SAKK CC for each update. This is not only necessary regarding new staff members, please also make sure to inform SAKK CC about leaving staff or change of trial responsibilities.*

After login you are led to the Welcome page:

3.1 The Welcome page and its functions

On the first page after login, you find information, links to other pages and documents.



1. User information

Here you can see your name and the current date. Check these details to make sure you haven't inadvertently logged into the wrong account.

2. Timer, Help and Logout

The **Timer** counts down the minutes left until your session will be terminated. After each switch of location or saving of data, you will be granted another 40 minutes.

Press the **Help** button to get an overview with details regarding all function within the taskbar.

Always use the **Logout** button to safely leave sT, without losing any data or blocking yourself for a return to sT for the next minutes.

3. Task bar (use the Help button to get an comprehensive overview of all functions)

The most important functions for you will be:

The Select Patient field – here you can find a specific patient by typing its UPN.

The UPN usually consists of the SAKK trial number (4 numbers) + underscore + patient number (3 or 4 numbers depending on the trial size) e.g. 2316_001 or 2316_0001.

New patient – here you can register a new patient (see section 4.1 for a detailed instruction).

Reports – here you can find all reports available for your trial e.g. a query report (see section 10 for a detailed instruction).

4. Manuals

Here you find a link to the **General user manual (GUM)** document.

5. Download Area

Here you find all **Trial Specific Manuals (TSM)** you have access to.

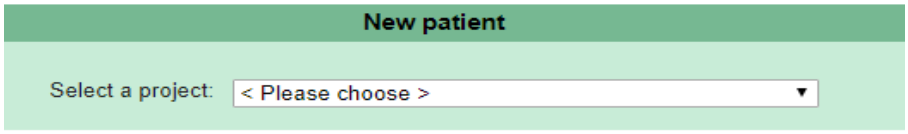
4. Set up of new patients in secuTrial, registration and randomization

4.1 Set up a new patient (UPN) in the system

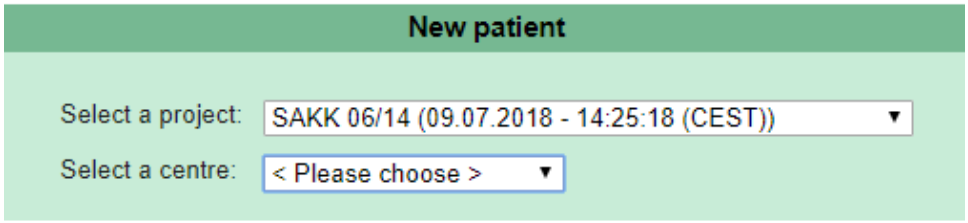
As a first step when registering a new patient, an UPN has to be created in the system.

*Click in the sT taskbar **'New Patient'***

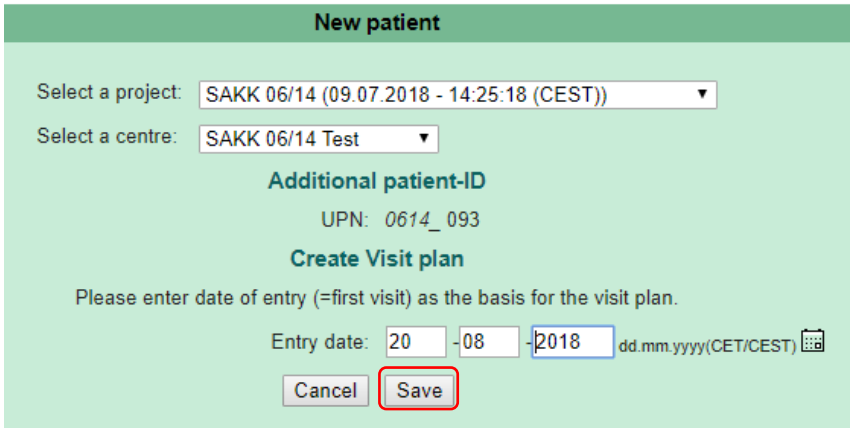
***Select the project** (trial number) from the drop down menu:*



***Select a center** (your site), if not already preselected:*



The window will expand to the following:



The system assigns the next available UPN automatically and pre-sets the Entry date with the current date.

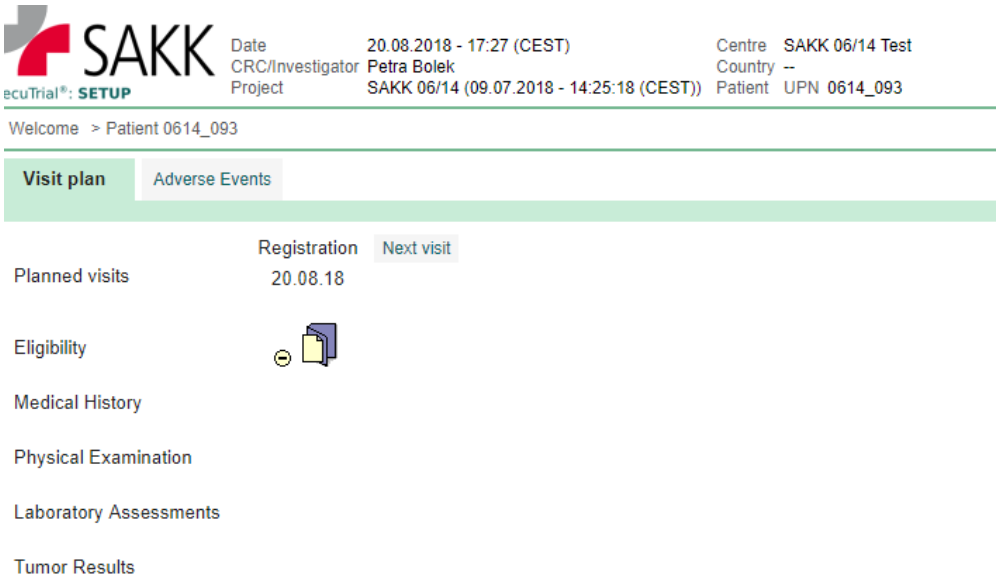
Usually you can find an information on how to define the Entry date. Follow up accordingly.

If there is no specific requirement how to choose the date, use the preselected one.

Save the data by pressing the '**Save**' button.

A pop-up window, informing about the successfully new patient set up, can be left by pressing the '**Continue**' button.

Subsequently, the system will open the patient's visit plan with the Registration visit forms.



4.2 Register a patient

The registration files* usually consists of 3 forms:

ER Information on patient registration

IE Inclusion / exclusion criteria

EV Eligibility evaluations

Or for newer trials (from 2020) of 2 forms:

EV Eligibility evaluations

ER Patient registration (and randomization)

Depending on the protocol, a Pre-registration might also be necessary. This would request a previous completion of ERP, IEP and EVP forms.

With exception of the newest generation trials (just 2 forms) the ER(P) form has to be printed, signed by the treating investigator and sent to SAKK CC.

To do so use the Save + close entry + print button at the bottom of the page.

- *In recent trials supporting checklists as defined in the trial protocol chapter 7 have to be completed before the eCRF forms can be filled in. In older trials eligibility criteria compliance might be recorded in detail within the eCRF. (Details regarding the valid process are to find in chapter 7 of the trial protocol)*
- *Registration eCRF forms have to be complete and correct. Otherwise, they cannot be saved and closed.*
- *The forms have to be processed in a consecutive way. It is not possible to fill in e.g. the EV form prior to the ER form.*
- *A form has to be saved and closed (DEC) before the next one can be filled in.*
- *Preferably, all registration forms should be completed the same day.*

After all forms are completed, saved and closed, an email will be sent to your attention, confirming the patient's registration.

**Please note the above listed registration files are used in recent trials.*

In older trials, the number and naming are different:

E1-E4; ER, EE, EI, EV

4.3 Randomize a patient

Depending on the trial protocol, a patient might need to be randomized.

- *To do so all registration forms have to be completed, saved and closed previously.*

The RA Randomization form is either already available or has to be set up by using the 'Next Visit' button (see section 6.3). In newer trials the randomization is included in the ER form.

The respective randomization form(s) have to be completed, saved and closed.

- *Like for registration, prior completion of supporting documents as defined in the trial protocol chapter 7 might be necessary.*

Pressing the Randomization button on the randomization form will trigger an email sent to your attention confirming the patient's randomization.

- *Like all prior eCRF registration forms the randomization forms have to be saved and closed. Otherwise, it will not be possible to set up following scheduled visits or complete baseline visit forms that require previous randomization.*

Please note: if not described differently in the trial protocol, registration and randomization should be performed the same day.

4.4 System availability & Contingency plan

The SAKK sT system is available 24/7. However, a short system reboot will be performed during the night (around 3:30h). In case of planned or unplanned maintenance downtimes, you will be informed on the login screen in time.

In case of any technical problems with the sT application, please contact your responsible CPM or CRA.

Patients need to be registered & randomized online.

In case the sT **system is not available** e.g. for technical reasons, it might be possible to perform the registration by completing an **Eligibility Form** (available on the SAKK portal) and sending it **via email to SAKK CC** (trials@sakk.ch).

Randomization can only be done online at the appropriate date. As sT might be available at SAKK CC even if not available at the site, please contact SAKK CC in case of technical issues.

For details and trial specific processes, see chapter 7 of the trial protocol!

In case a new patient was created by mistake or it was only realized at the time point of registration that the **patient is ineligible, contact the SAKK CC.**

Multistage registration and randomization procedures might require completion of a **screening failure form** in case of erroneously registered patients.

For details and trial specific processes, see chapter 7 of the trial protocol.

A further source regarding screening failures handling is the TSM.

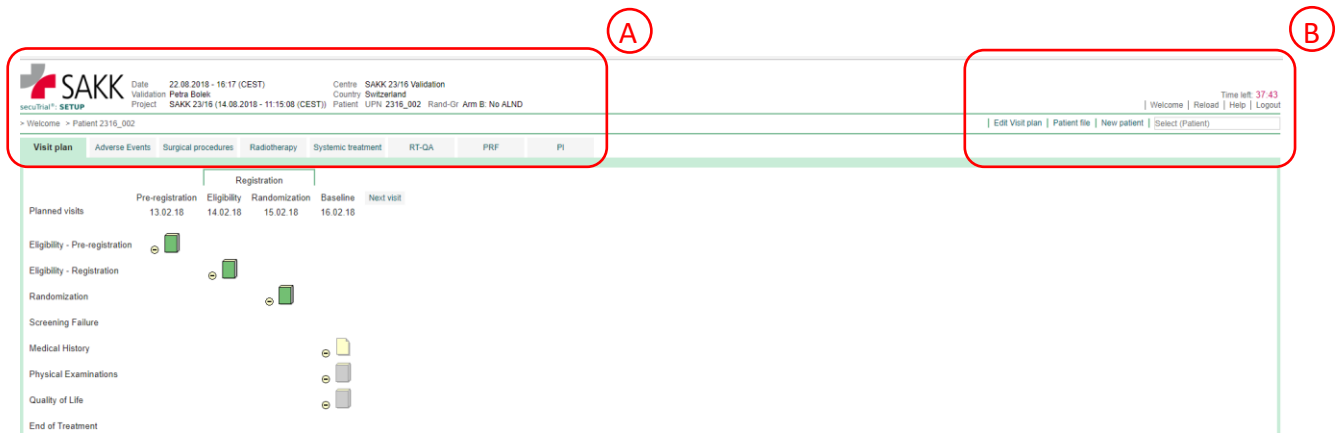
A retrospective assignment of a patient to an UPN is not possible.

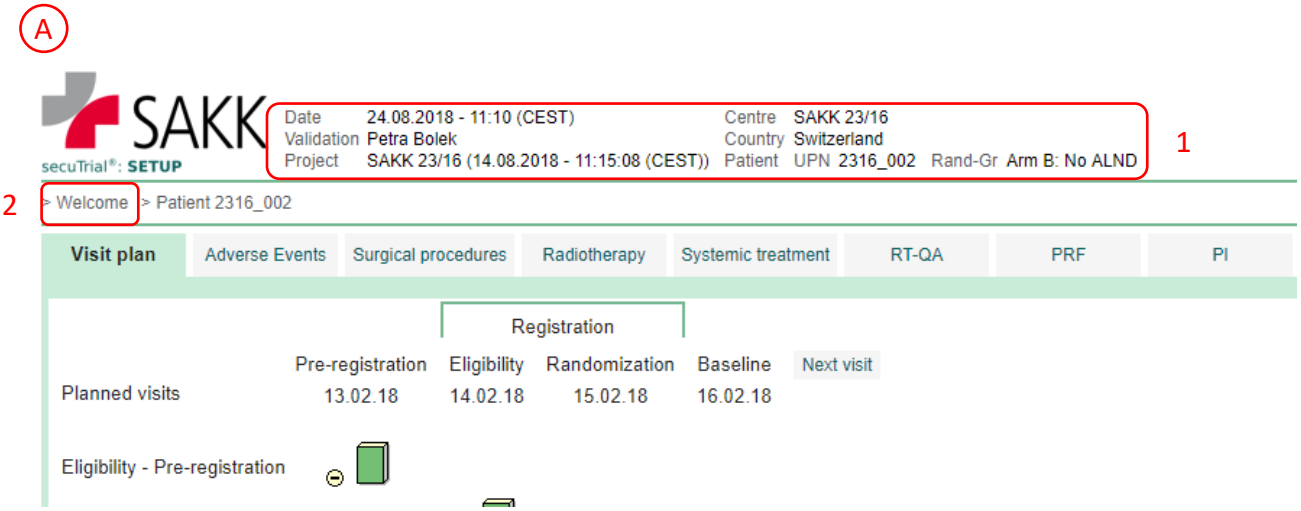
(UPNs should not be created ahead. Erroneously registered patients should not be used to record data of later patients)

The patient identification list maintained by the site is the only link between the patient's identity and the UPN.

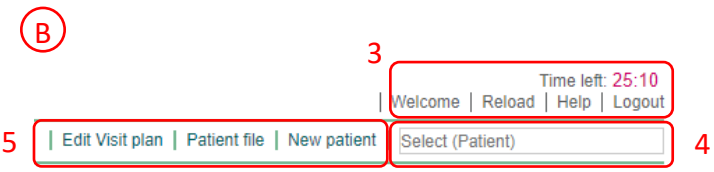
5. Form Overview

After a new patient was successfully set-up, the system opens the patient's overview.





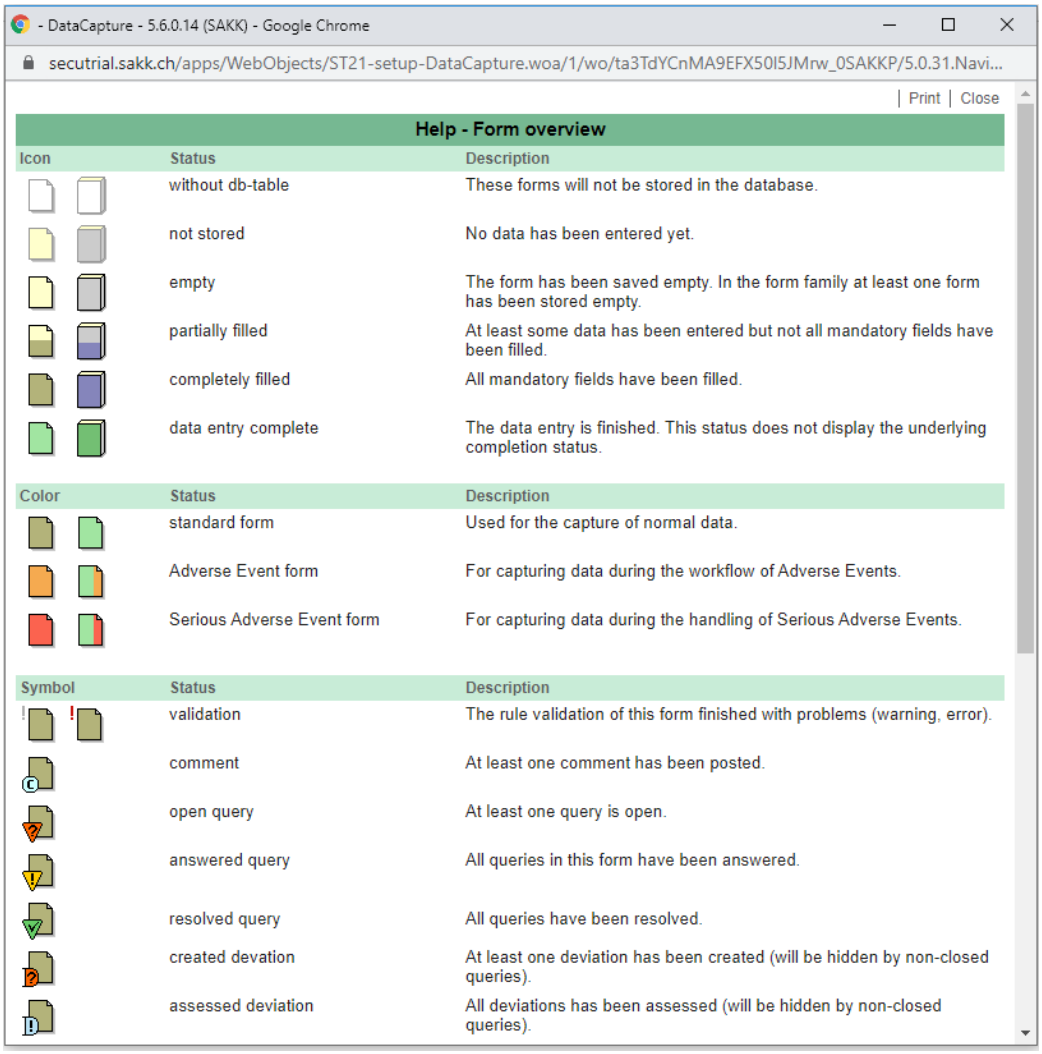
1. Important Information regarding Trial, Patient, logged in Person, etc.
2. Navigation option to '**Welcome**' page.



3.

a. **Time left** – shows how much time is left until automatic log out
b. Navigation option to '**Welcome'** page

c. **Reload** option to refreshes the current page
d. **Logout** option to leave sT in a safe manner
e. **Help** option provides an overview of possible form status:



4. Select (Patient): type in UPN to get directly to that patient's 'Visit plan'.

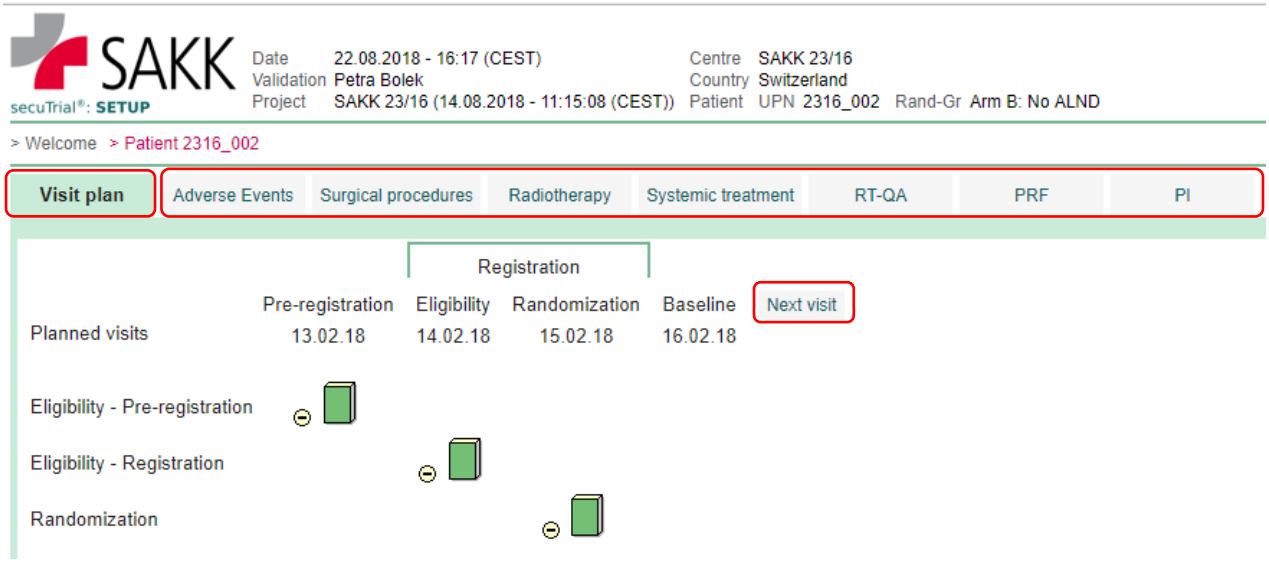
The UPN usually consists of the SAKK trial number (4 numbers) + underscore + patient number (3 or 4 numbers depending on the trial size) e.g. 2316_001 or 2316_0001.

For few trials there is also site-specific documentation available. To get there type instead the UPN the USN and chose the respective study number if more than one are available.

The USN usually consists of a county identifier and the Site number e.g.
CH-0001 Kantonsspital St. Gallen,
AT-0103 Tirol Kliniken- Landeskrankenhaus Innsbruck

5.

a. **Edit Visit plan** (see 6.1)
b. **Patient file** to create a PDF or HTML file with all completed forms of your patient(s).
c. **New patient** (see 4.1)



6. The **Visit plan** includes all scheduled visits and associated forms.

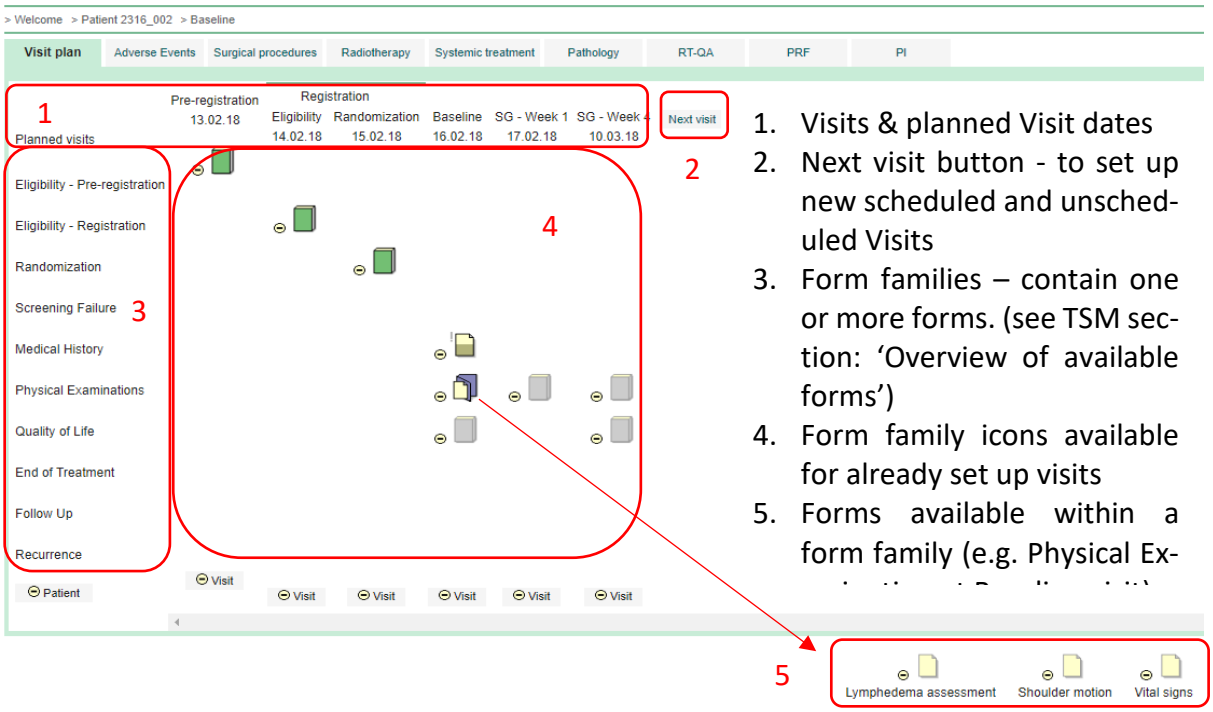
It covers all examinations that have to be performed in a consecutive way, at a defined point in time.

New visits will be created pressing the **'Next visit' button**. (see figure above)

7. Beside the Visit plan, there are the existing so called **Casenodes**.

On Casenodes, assessments are documented on an ongoing basis and/ or at variable points in time (for details, see section 8).

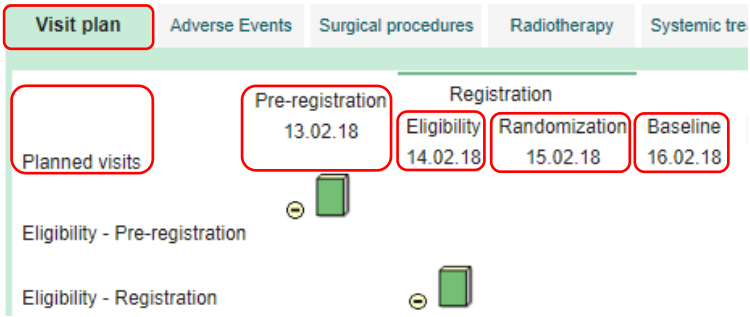
6. The Visit plan



1. Visits & planned Visit dates
2. Next visit button - to set up new scheduled and unscheduled Visits
3. Form families – contain one or more forms. (see TSM section: 'Overview of available forms')
4. Form family icons available for already set up visits
5. Forms available within a form family (e.g. Physical Ex-

The **visit plan** provides an overview of a patient's visits. It follows the **trial protocol and the trial scheduler** (Excel sheet), which can be downloaded from the SAKK portal.

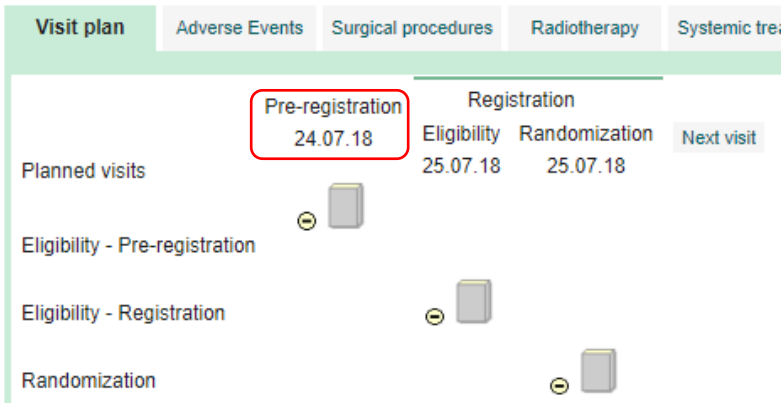
Allocated to each planned visit is the planned visit date. This date is calculated on basis of the date a patient was created in sT.



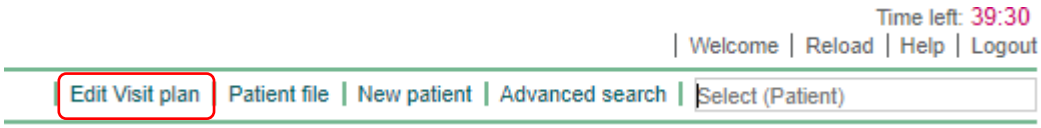
- *To use the "planned visit dates" as a helpful orientation during the course of the trial, they needs to be correct. Therefore, the entry date of a patient needs to be identical with the date of the first visit - (pre)registration as long as the trial protocol does not request something different.*
- *Whenever a visit took place at a different date than the planned one according to the scheduler and the trial protocol allows a shift of future visits relatively to the registration date, the visit date can be adjusted.*

6.1 Edit visit plan dates

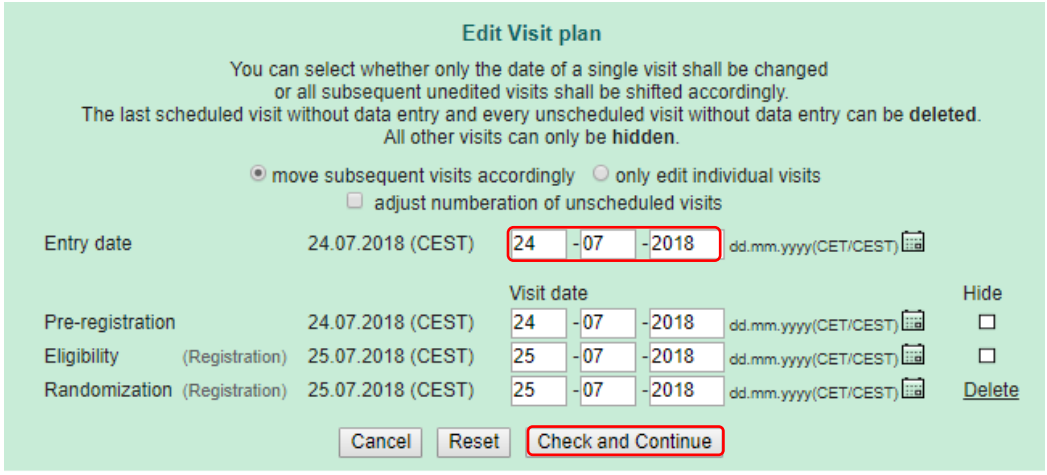
As an **example** we have the following situation – a patient was created on 24.07.18, hence the first visit here - Pre-registration comes with the date 24.07.18. For some reason the Pre-registration actually has taken place later on 25.07.18. Therefore, the entry date should be adjusted accordingly.



*To do so click on the 'Patient Overview' on the right hand site the '**Edit Visit plan**' option.*

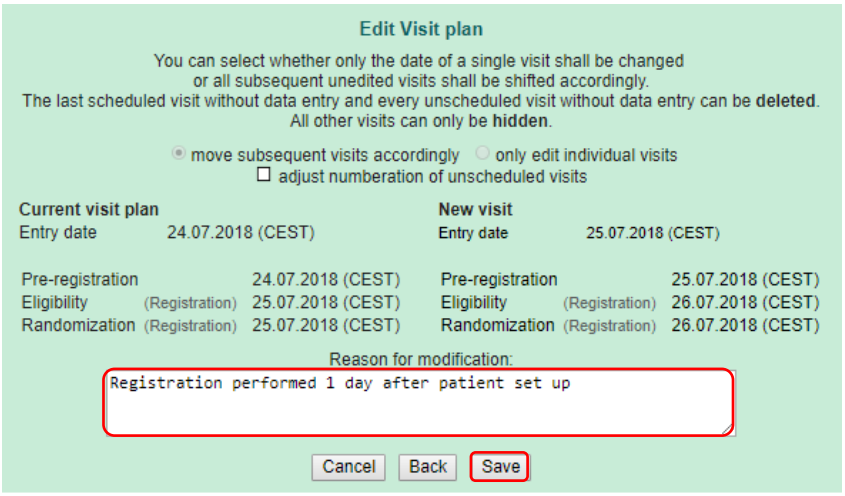


The following window will appear:



*Correct the Entry date to the 25.07.2018 using the predefined option '**move subsequent visits accordingly**' and click button '**Check and Continue**'*

This leads to the next pop-up window. Which needs a reason for modification and can be saved, if all is correct.



Subsequently the Visit plan will look like this:

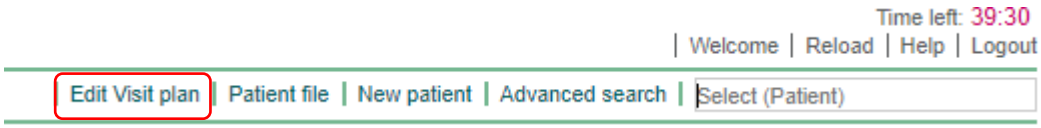
Please note: A visit name cannot be corrected! If you have recorded data within the wrong visit, you have to delete all data from the respective forms and record them in the correct visit.

6.2 Deleting visits

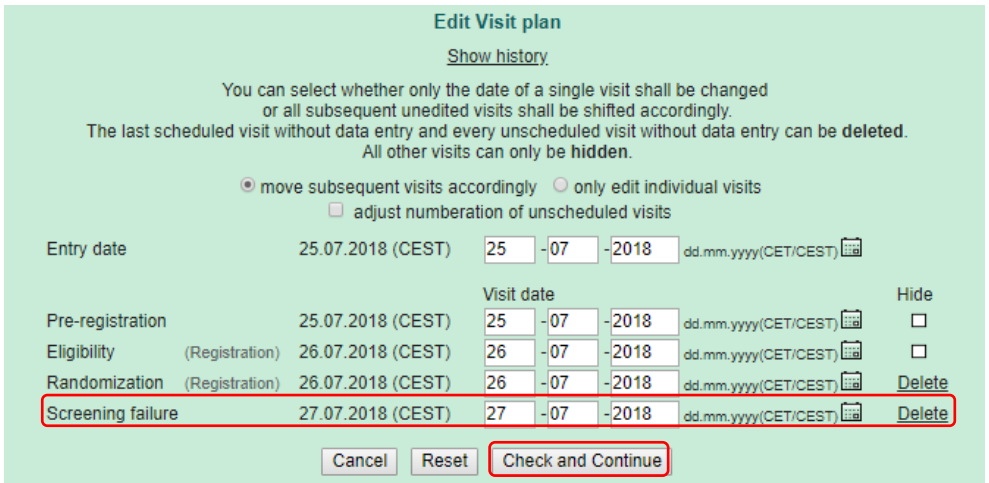
In case, a visit had been created erroneously and none of the respective forms have been modified (left by using the 'Save' button), the respective visit can be deleted entirely.

For **example** a Screening failure form (SF) was created accidently and needs to be deleted.

*Do so by clicking on the right hand site the '**Edit Visit plan**' option.*

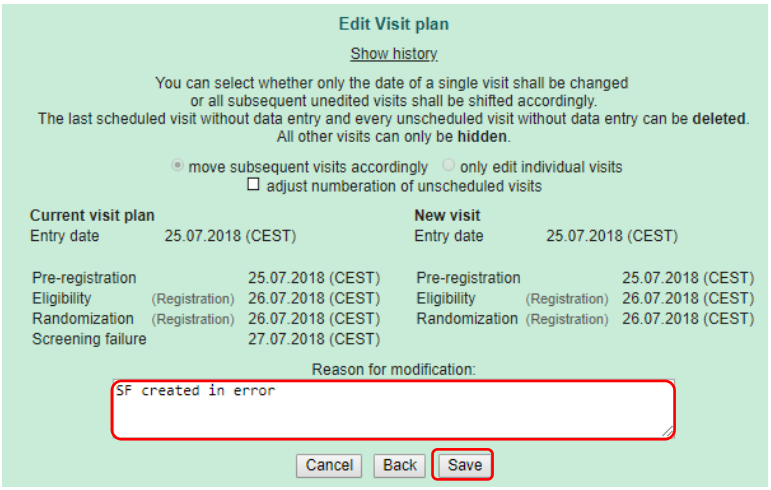


The following pop up window will appear:

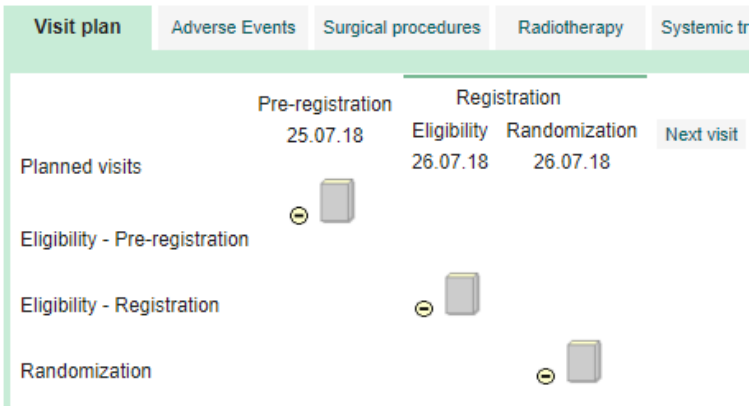


*By choosing the Screening Failure form and pressing '**Delete**' the record will disappear. To finish the process additionally press '**Check and Continue**'.*

*This leads to the next pop-up window. Which needs a reason for modification and can be **saved**, if all is correct.*



Subsequently the Visit plan will look like this:



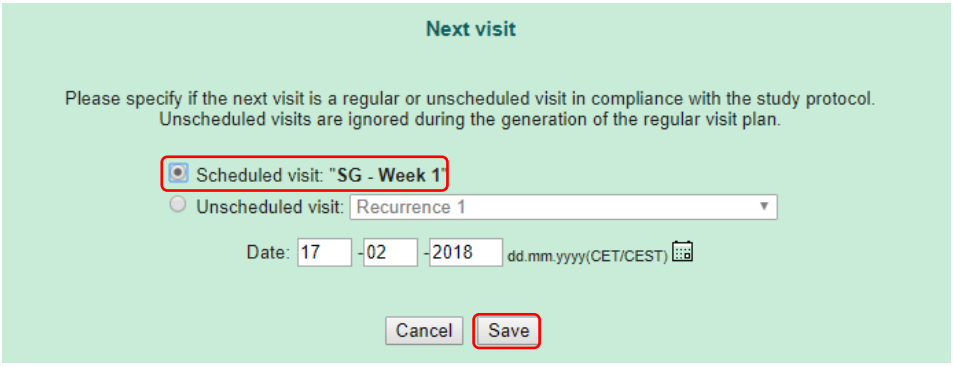
6.3 Adding scheduled visits

To add the next scheduled visit press the **'Next visit'** button on a patient overview.

A window pops up, pre-set on the next available scheduled visit (SG-Week 1 in the figure below)

By pressing the '**Save'** button this visit will be available within the 'Visit plan'.

As long as no data has been saved in the newly created visit (not even a bank form has been saved), this visit can be deleted entirely. In case a visit was created by mistake, immediately delete the visit as described in section 6.2



6.4 Adding unscheduled visits

To add an unscheduled visit use the **'Next visit'** button, switch from 'Scheduled' to **Unscheduled visit**' and choose the visit needed from the drop down menu.

Adjust the visit date if necessary and save data.

As long as no data has been saved in the newly created visit (not even a bank form has been saved), this visit can be deleted entirely. In case a visit was created by mistake, immediately delete the visit as described in section 6.2

Details regarding required unscheduled visits are described in the trial protocol and TSM.

7. Data Entry

All eCRF forms have to be completed online by the site staff.

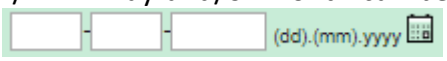
Exceptions from this are Serious Adverse Event (SAE) and Pregnancy report (PRF) forms.

These forms are only available on paper for site staff and need to be send by email to SAKK CC.

For details, see trial protocol chapter 10 &11.

Paper forms sent to SAKK CC will be entered into sT trial database by the responsible SAKK staff.

7.1 Important data entry rules

- All data need to be recorded in **ENGLISH language**.
- Start the **first word** in a free text field with a **capital letter**.
- Record **dates** in the format: DD/MM/YYYY. Day and/or month can be left blank (only if not known) when indicated by brackets. 

  In older trials, the following convention is in place and will be kept:
  Missing days have to be recorded as 15. In case only the year is known day and month should be recorded as 30.06. (June).

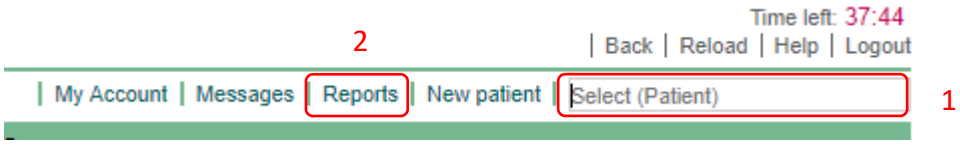
- To document **medication** use the **English GENERIC name**, not the brand name.
- Indicate **missing data or entire assessments** by ticking the respective **'Not Done' box**.
- **Implausible data** will trigger **'Warnings'** in red color. To avoid queries, **do NOT ignore them**. Follow up immediately and provide / correct respective data before saving.
- Whenever data definitely can't be recorded as requested and a comment field is available on the respective form, **add a meaningful comment to explain and confirm the (missing) data**. That helps avoiding queries.
- After completing a form always **save data before leaving** and **close the form as soon as all data are recorded**.

  Forms that do show Warnings have to be saved twice! *(See section 7.5)*

- To get an overview of the required visits and to calculate visit dates **use the official trial Scheduler**. It can be downloaded from the SAKK portal.

7.2 How to access patient's data.

A patient's data recorded in sT can be accessed in two ways from the 'Welcome' page:



1. Type the Patient Number (UPN) into the field '**Select Patient**' and press Enter. This opens directly the respective patient's overview (Visit plan & Casenodes)
2. Click '**Reports**' and open on the reports page report: **1.0 Patient Overview**. Here you get an overview of all patients belonging to your site.

   A click on the patient's UPN opens the respective patient overview (Visit plan & Casenodes)

To switch from one patient to another use the '**Select Patient**' option or use the Patient Overview report, which remains available until a new report will be opened.

7.3 How to access a Patient's forms

In the TSM all form families with forms and sub forms are listed in one table (section: 'Overview of available forms'). It provides an overview, where data required by the protocol can be added to the eCRF.

Click on a form family icon.

If it only contains one form,  it opens directly.

If it contains more than one form,  it opens  and all forms are displayed below the visit plan. Click on one of these forms to open it.

(To help identify forms see first figure section 6)

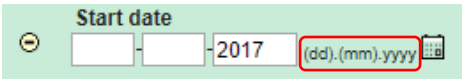
7.4 Recording data

- All data need to be recorded in **ENGLISH language**.
- Start the **first word** in a free text field with a **capital letter**.
- To document **medication** use the **English GENERIC name**, not the brand name.

Dates

Record dates in the format: dd/mm/yyyy

- *For some dates, days or days & month are not mandatory.*
- *Brackets around the respective placeholders indicate this. Example:*



- *As days and month do not need to be recorded if not available, fill in the year as a minimum and leave day & month fields blank.*

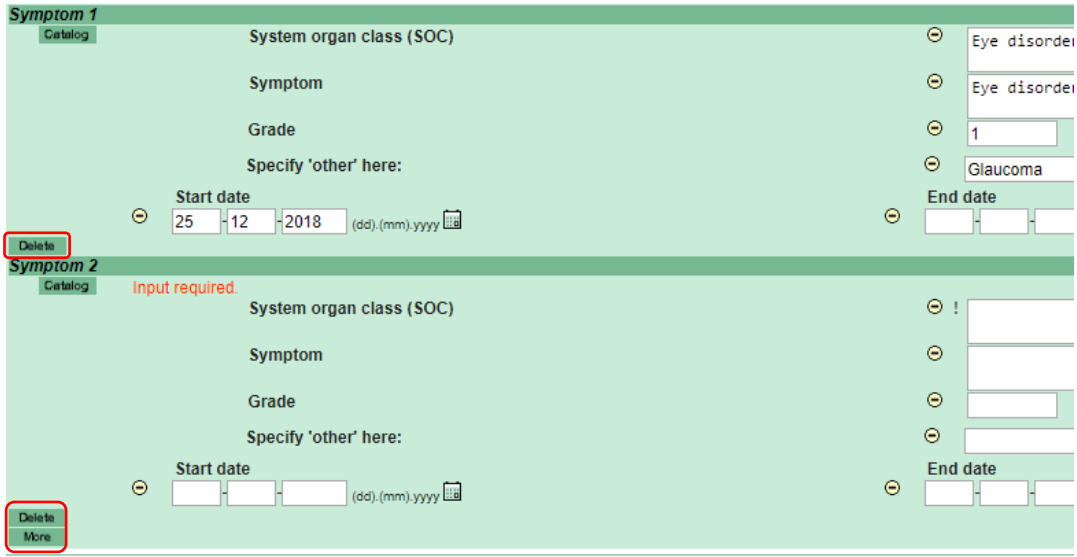
In older trials, the following **convention** is in place and **will be kept**:

- *Missing days have to be recorded as 15. In case only the year is known, day and month should be recorded as 31.06. (June).*

Add/ delete records - Repetition groups

On some forms e.g. AE, Concomitant Medication, Baseline Symptoms, etc. it is possible to add as many records as needed.

- *To do so click the '**More**' button on the left hand side.*
- *As long as data have not been Source Data Verified (SDVed) or no query is allocated to the form, it is possible to delete the created record by clicking the '**Delete**' button on the left hand side.*



Scores

On some forms there are Scores automatically calculated. This happens either after data have been recorded and the button '**Score**' has been used or latest when the form is saved/closed.

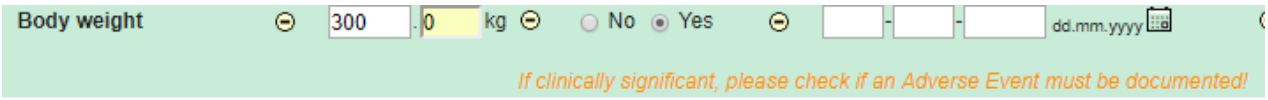
Missing data

Missing data can usually be indicated as such (exceptions are the Eligibility and Randomization forms).

- *Entire forms, which cannot be completed, should be marked as such in the header section. Usually there are questions like 'Was xxx performed? = yes/no'*
- *Single values that are not available can usually be marked with 'Not done' if other values on the same form can be delivered.*
- *If there is no such option, the requested data should be delivered whenever possible. If the data are actually not available and a comment field is on the form, please confirm there, that the data are missing and provide the reason why. (See Comment Section below)*

Heads-up messages

Some data records will trigger a heads-up message (in orange color). E.g. clinically significant ticked Lab values: 'If clinically significant, please check if an Adverse Event must be documented!'



- *Please note these sentences will remain even if the requested task is fulfilled.*

Laboratory data – recording upper/ lower limits (ULN/LLN)

In new trials (from 2020) ULL/LLN will be available on each laboratory form.

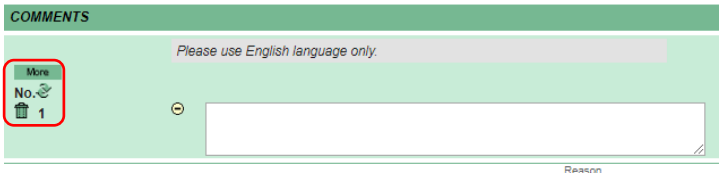
- *ULL/LLN values have to recorded once in the beginning of a trial.*
- *When the following Lab form will be opened the first time, ULL/LLN values will be transferred.*
- *Please check ULL/LLN values for correctness and completeness and update if necessary.*
- *As the ULL/LLN data are only copied from the previous Lab form, they will be missing if the previous Lab has not been performed or single values are missing.*

  In this case, they need to be manually recorded again on the current form.

  Please make sure to do that before opening following Lab visits, as data will be transferred only when opening a lab form the first time, otherwise you have to complete data manually for more than one visit!

Comment Section

The majority of forms come with a comment section on the bottom of the page.



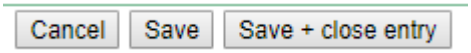
- *Do not record regular data here.*

- *Use this comment field to provide extra information or explanations regarding recorded data.*
- *It can also be used to avoid queries by confirming inappropriate or missing data and providing a meaningful comment explaining why the data are as they are.*
- *Comment fields can be added using the 'More' button or deleted using the trashcan symbol. All generated comment fields do get a consecutive number.*

7.5 Saving data

After the data entry is finished, the data need to be saved!

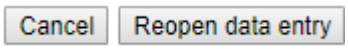
On the bottom of each form there are the following buttons:



- *Click '**Save**' if you just want to save data on a **form not entirely completed** yet.*
- *Click '**Save + close entry**' to **finish a form**.*

Forms closed do change their status to not editable anymore. The file color also changes to green.

As long as forms are not Source Data Verified (SDVed) and no Query is attached to them, they can be reopened by using the button '**Reopen data entry'**.



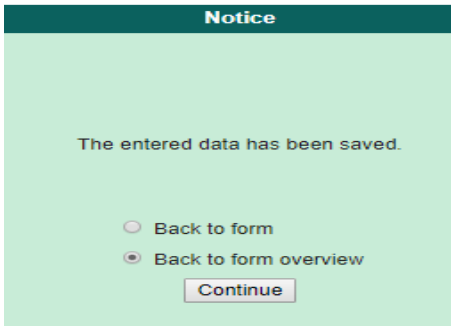
When saving or closing a form it is possible that so called '**Warnings'** appear.

These are information in red color, allocated to data fields, which do miss data or have wrong or inconsistent data recorded. When this happens, immediately provide / correct the data whenever possible and save /close the form again.

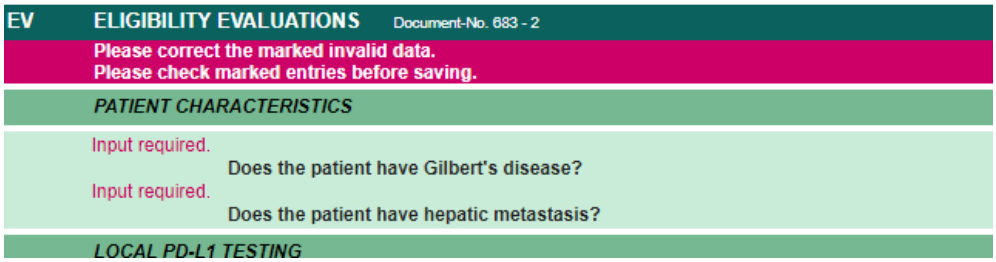
Saving data although 'Warnings' are on the form

Sometimes it is not possible to provide all data at once. In this case 'Input required' 'Warnings' will appear. To leave the form without losing data, the save process will have to happen in two steps:

- *Press the '**Save'** button after recording data. This will trigger the appearance of '**Warnings'** on the form. If you cannot resolve them immediately,*
- *press the '**Save'** button a second time. Now you will get a pop up window confirming that data have been saved as well as navigation options.*
- *After choosing where to go next, press the '**Continue'** button to leave the pop up window.*



Sometimes it is **not possible to save a form**, when **'Warnings' are present**. This happens mainly on Registration and Randomization forms but is not limited to them. If this happens, a red box will appear on top of the form not only asking to check data but to **correct** them.



If this is not possible, the only way to leave the form is by using the 'Cancel' Button.

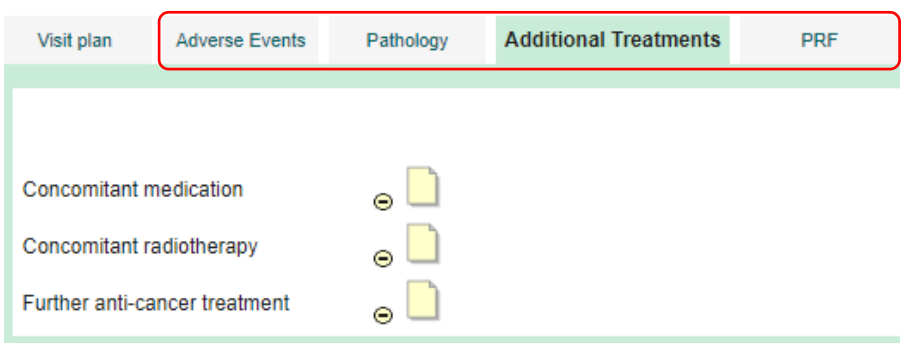
8. Casenodes

Casenode forms are located on separate tabs, next to the Visit plan.

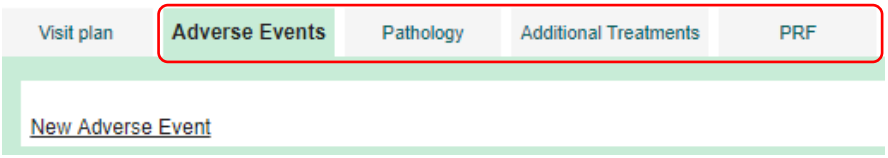
Typical Casenodes are Adverse Events and Concomitant Medication. Depending on the trial, there can be others too.

Casenodes are used to record data, which have to be collected on an ongoing basis and/or can be produced at any undefined time point during the trial process.

Casenodes can be completed when required by simply choosing the respective tab and opening the already available form(s)…



… or creating new events as e.g. for AEs by clicking a provided link.



Casenodes, available as forms always contain a header question asking for performed examinations, administered medication etc. This question has to be answered latest at the End of Treatment for a patient.

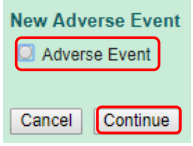
Casenode Adverse Events

- AEs have to be recorded according to trial protocol chapter 10.
- For each SAE reported according to trial protocol chapter 11, an AE form has to be completed in addition.
- AEs, which happened prior to start of trial treatment, are considered as Baseline symptoms (see definition in trial protocol chapter 10 & **12**).
- Baseline symptoms are documented separately under the form family: Medical History.
- Baseline symptoms which are worsening after treatment start have to be documented as AEs from the time point of the worsening (Check Protocol for possible restrictions regarding this rule).

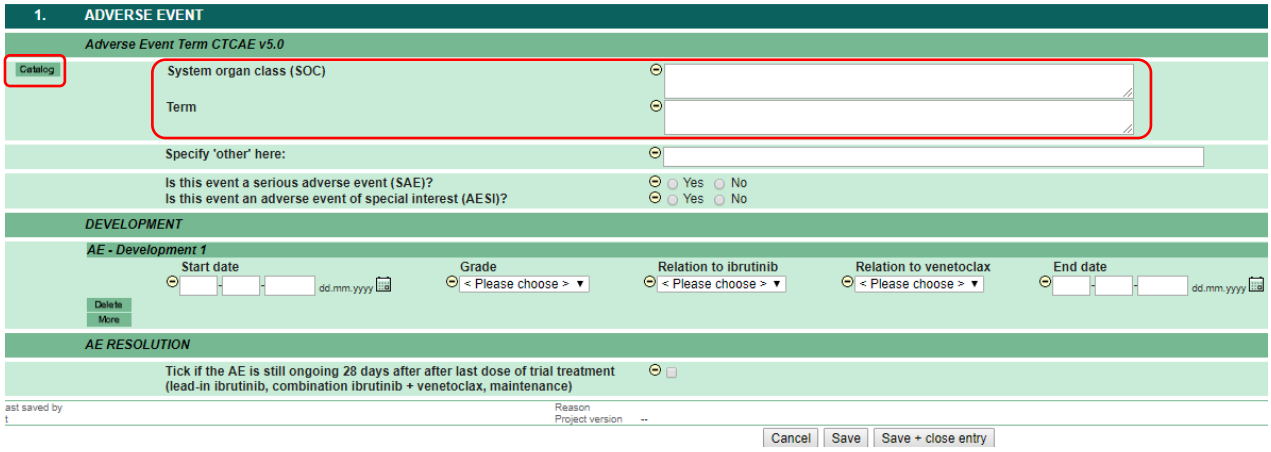
How to document AEs

*Click on Casenode tab Adverse Events. Then click on link **'New adverse Event'**.*

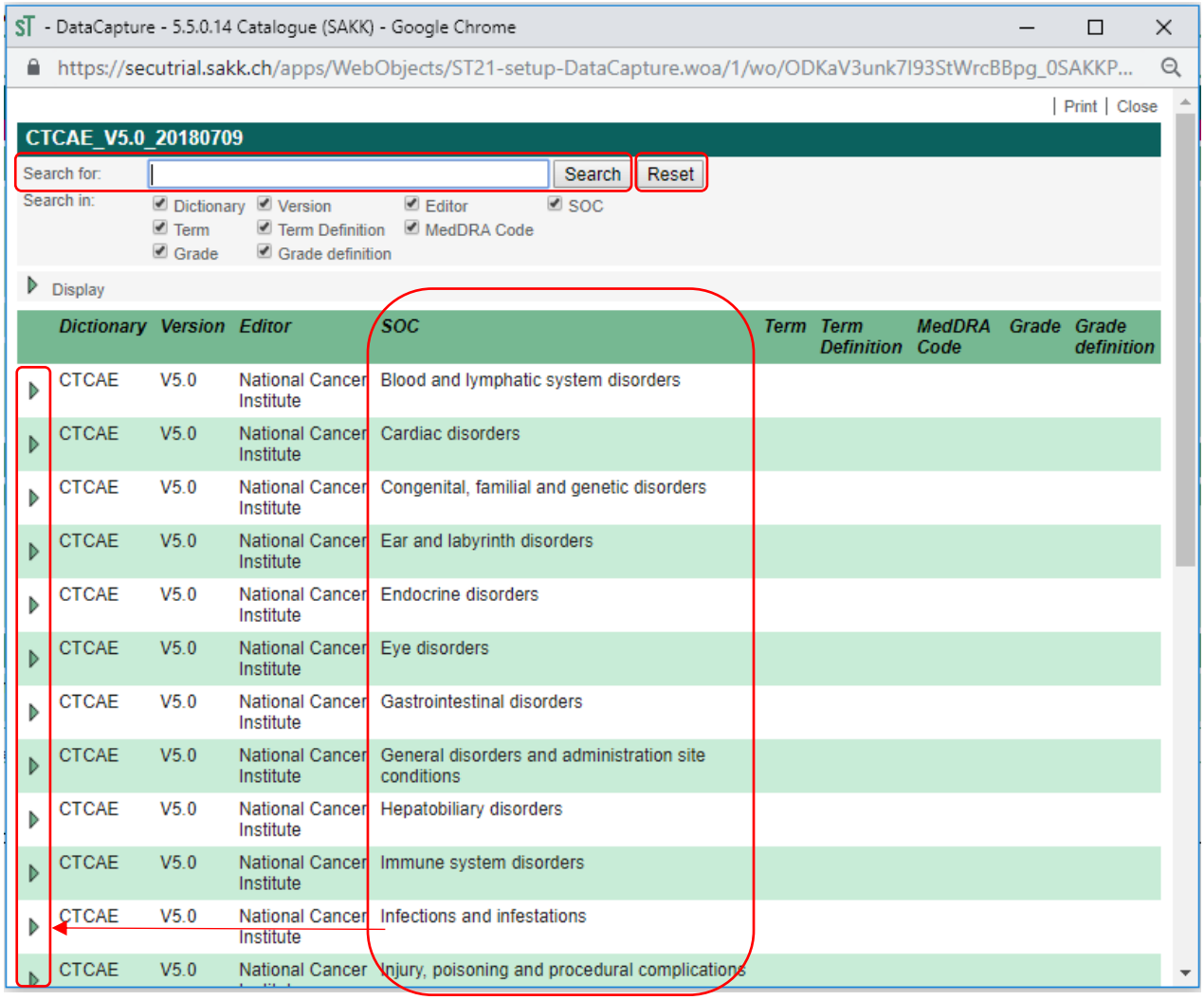
*On an appearing pop-up window, click again **Adverse Event** and button **'Continue'**.*



An Adverse Event form similar to the one below opens.

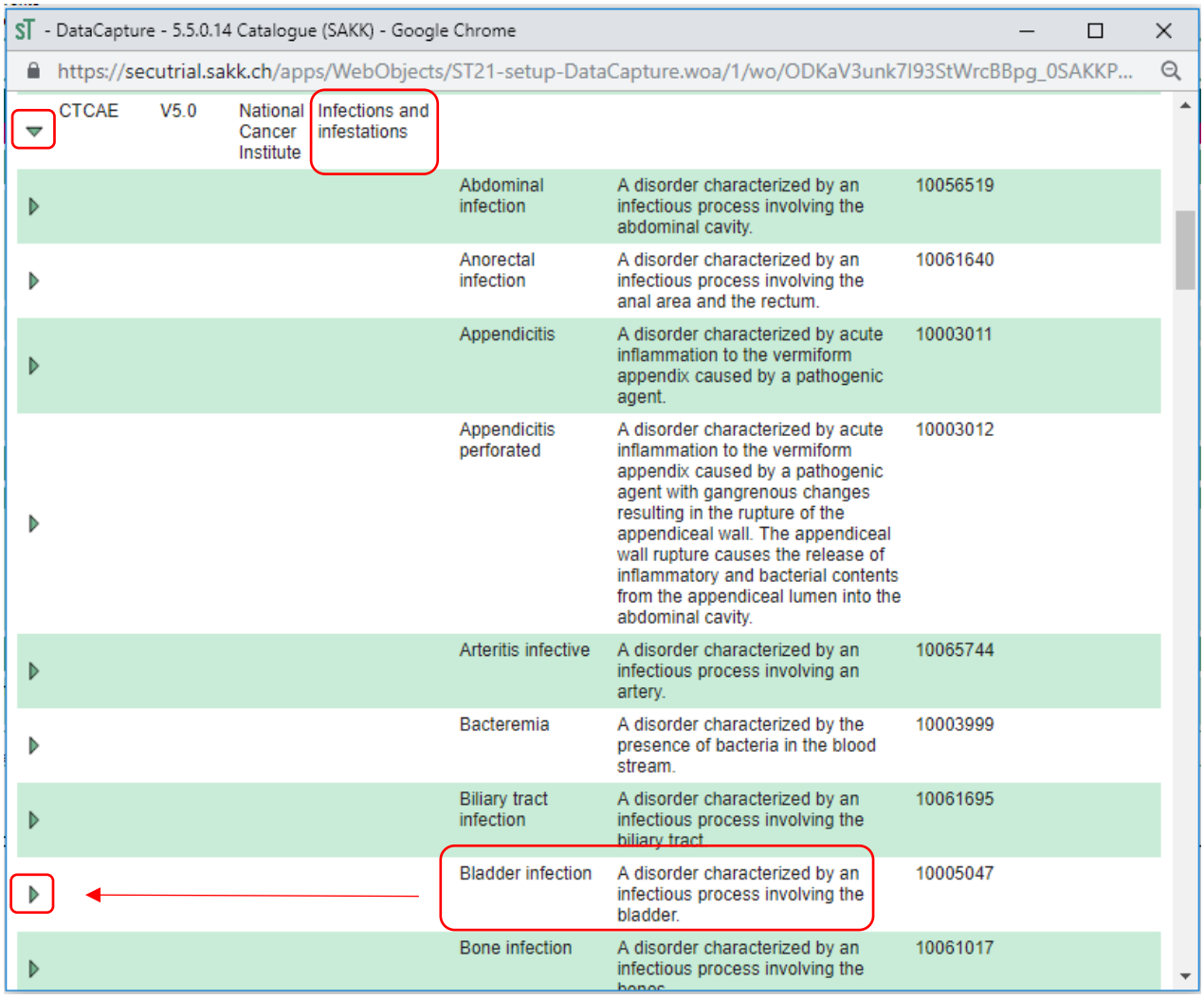


- *Start recording the AE by clicking on the button **'Catalog'**.*
- *A pop-up window with the current **CTCAE catalog** opens.*
- ***Searching for** an **AE 'SOC' & 'Term'** can be done different ways:*



Searching via SOC:

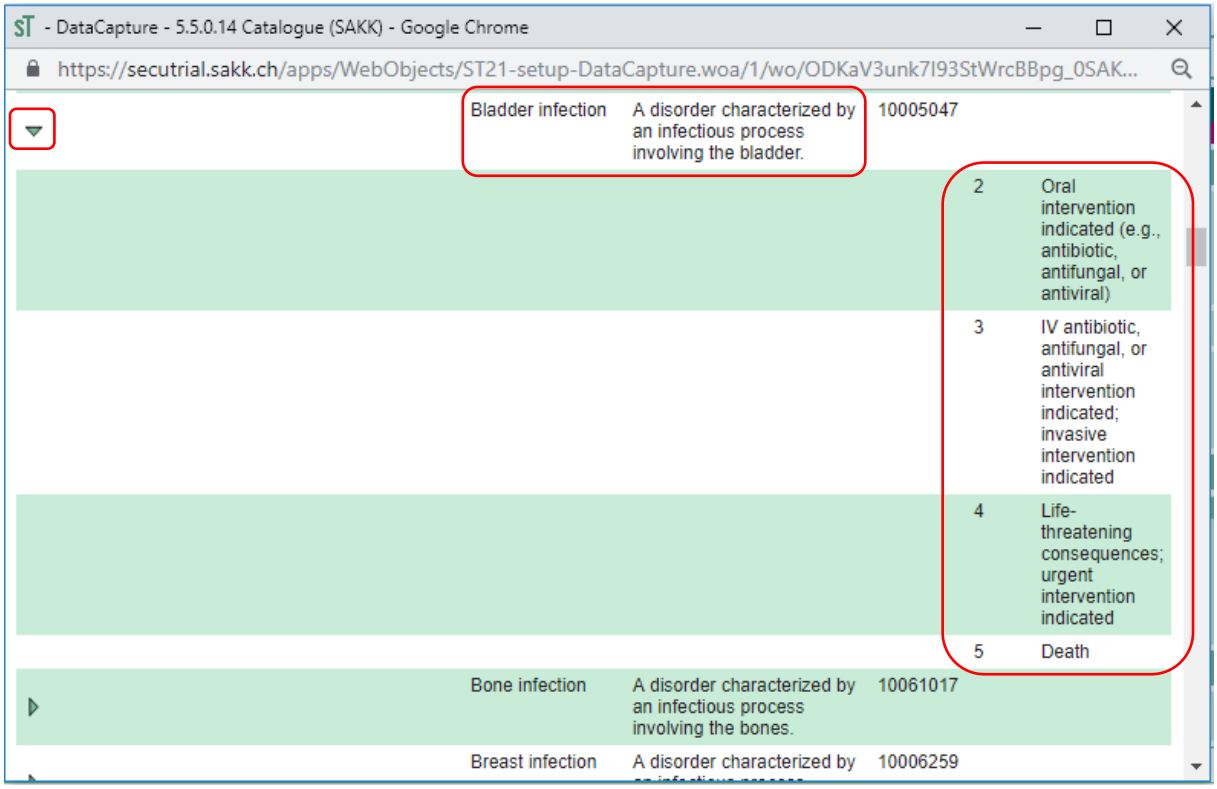
- *Choose a possible SOC and expand its sub menu by clicking on the respective triangle on the left hand side.*
- *Do not click directly on the SOC term, as it will bring you back to the AE form and only populate the SOC!*
- *For an example, when searching for the term 'Bladder infection' the SOC 'Infections and infestations' can be chosen:*



- *Bladder infection can be found here. By directly clicking on the term the AE form will be completed with both 'SOC' and 'Term'.*

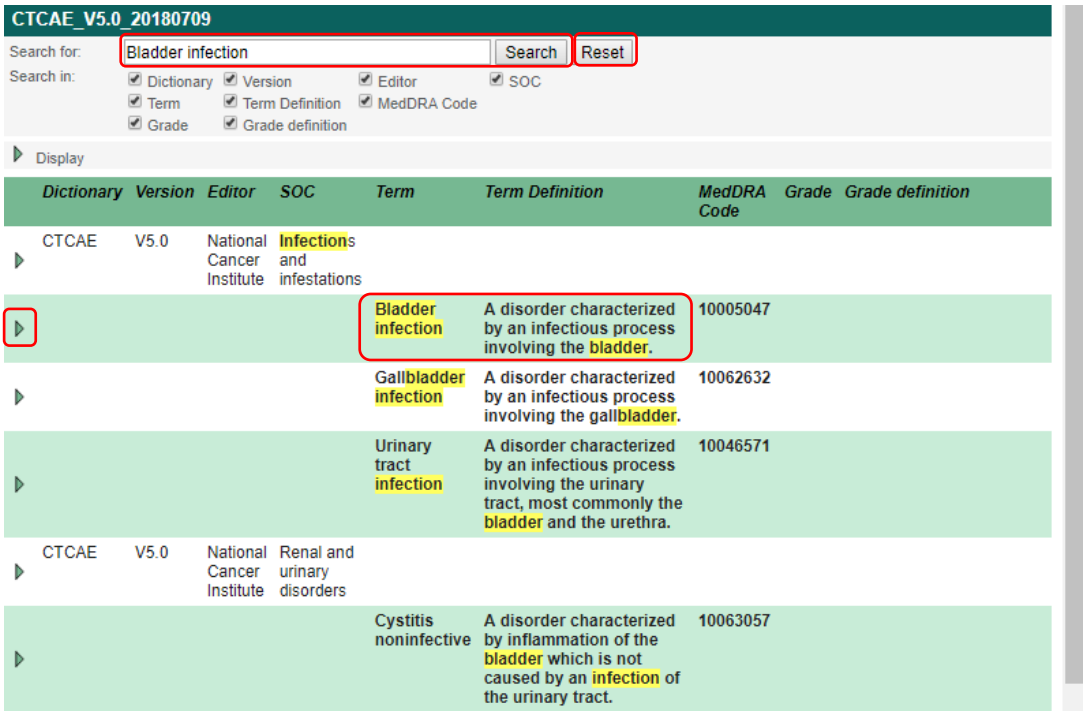
- *To find out about **possible grades** allocated to this **'Term'** and the grades definition, click the associated triangle.*
- *Here (picture on the next page) we learn that 'Bladder infection' has only 4 possible grades associated in CTCAE:*

  Grade 2-5. This needs to be considered when recording the grade on the AE form.
- *To paste 'SOC' & 'Term' into the AE form click either on the **'Term'** or one of the associated grades. **The grade has to be manually recorded on the AE form.***
- *In case you have not found the correct **'Term'** or clicked by accident a wrong one. Open the Catalog again and click on top of the pop-up window next to the search window the button **'Reset'**. This allows a new search. (second picture on the next page)*



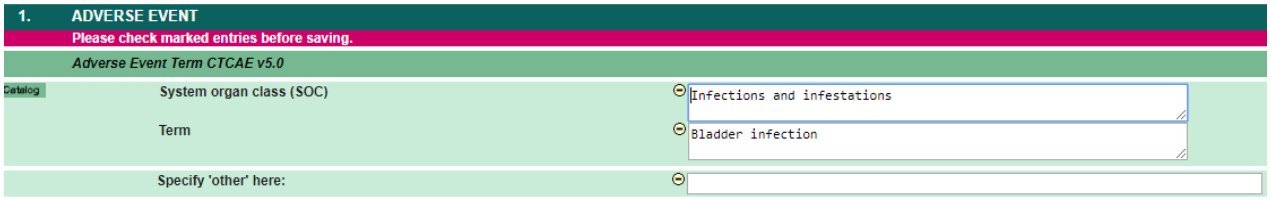
Another option would be to search for the **'Term'** directly with help of the **search window** on top of the pop-up window. All 'SOC' and 'Terms' with 'Bladder' respectively 'Infections' will be marked in yellow.

Click the correct one or look previously for possible grades by using the associated triangle on the left hand side.



Choose the term and 'SOC' and 'Term' will be recorded on the AE form.

If both are completed, and '**Term' is already specified** in detail, **do not fill in** the additional field "**Specify 'other' here**".

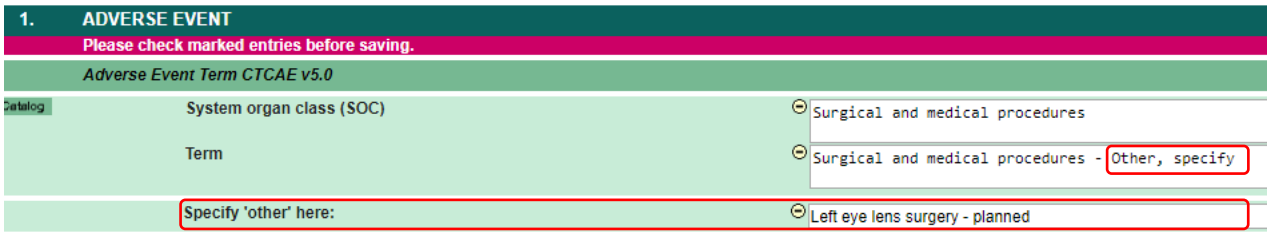


Sometimes the AE term required is not part of the CTCAE.

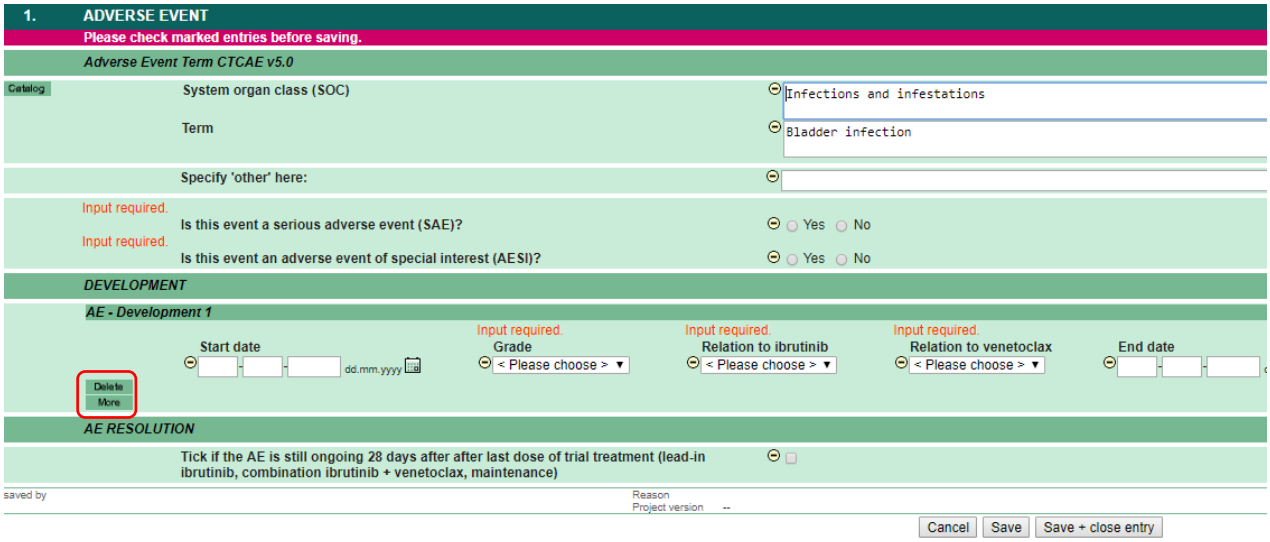
ONLY for those cases each '**SOC'** sub menu contains at the very last position the '**Term'**:

SOC name – Other, specify.

If it is used, provide a meaningful specification in English language in the additional field "Specify 'other' here".



As soon as 'SOC' and 'Term' are recorded, all other data are indicated as required



Determine whether the AE is actually an SAE by answering the question 'Is this event a SAE? = Yes/No'

If applicable, determine whether the AE is an AESI or any other question asked.

*Record the actual AE with **Start date, Grade** (make sure the grade is available for the AE according to CTCAE), **Relation to study drug** and **End date or Ongoing** (depending on the trial, there may be more than the listed items to be completed).*

*If **stop date/ongoing is not clear** at the time of recording, the form need to be saved although a **'Warning'** is available (**the Save button has to be used 2 times; see section 7.5**).*

Revisit the form as soon as the end date is available or the follow up period of ongoing AEs after trial treatment is completed as defined within the protocol chapter 10, in order to indicate that the AE is resolved or still ongoing.

*Whenever the AE is changing in grade or it stops and starts over later again, this is considered a **development** and need to be recorded **within the same AE form**.*

*The only **exception** from this is when an AE is considered as an **SAE**. In this case it needs to be recorded on a separate AE form.*

Example: an AE starts as grade 2 on 01.01.2019

Then it worsens on 05.01.2019 and the patients need to be hospitalized for 3 days – which means this needs to be reported as SAE and additionally as AE with tick SAE = yes.

After hospitalization on 08.01.2019 the patient still has weak symptoms for another week before the AE finally stopped at 15.01.2019.

*This would mean you have to **complete 2 AE forms**:*

AE form 1) *Start 01.01.2019-Stop 04.01.2019 grade 2*

Start 08.01.2019- Stop 15.01.2019 grade 1

For both AE records the question: 'Is this event an SAE' = 'No'

AE form 2) *Start 05.01.2019- Stop 07.01.2019, grade 3*

For this AE record the question: 'Is this event an SAE' = 'Yes'

Previously, an SAE (paper) form had been completed for the time from 05-07.01.2019.

Make sure the data on the SAE form and the respective AE form do match.

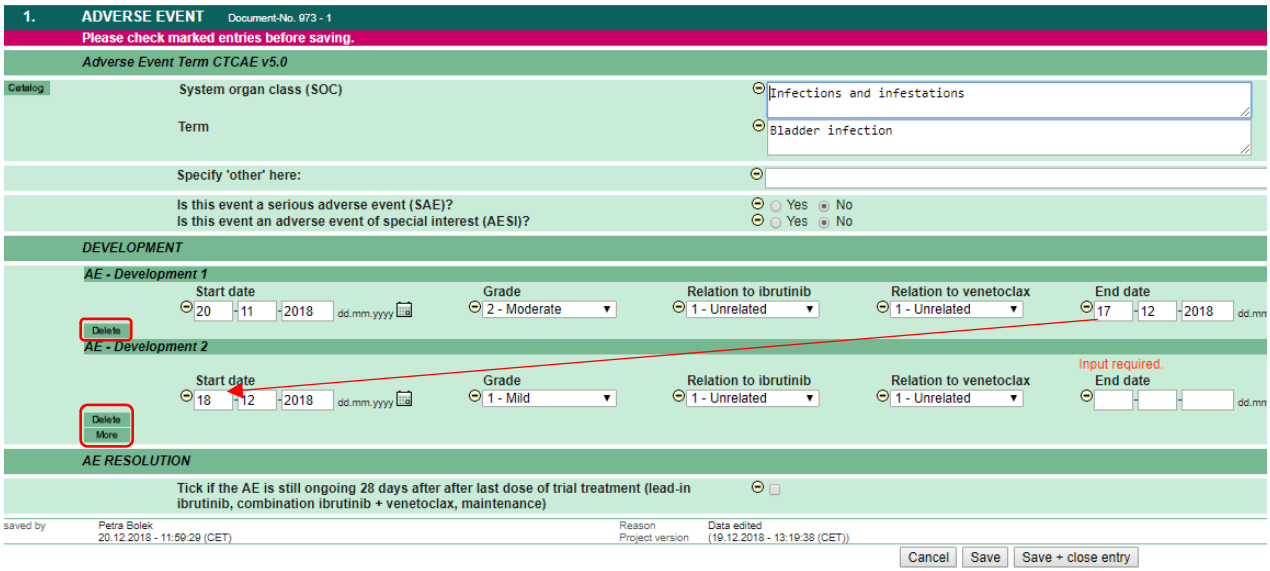
(SOC/Term, Start/Stop/ongoing, Grade)

Already running trials might use a different approach. Please contact your responsible CRA in case of any doubts.

*To document a development click the **'More' button** to add a new line.*

*As long as the form is not Source Data Verified (SDVed) or a query is set on it, records can be deleted entirely by using the **'Delete' button**.*

*When adding a **development record** make sure, the records are **not overlapping**. The start date of the latter record needs to be after the end date of the previous one.*



*In case the **exact dates** for start and/or end date are **not known**, enter the following dates:*

Start date - should be the date one day after the last visit, the AE had not been available / the grade had not been changed.

End date - should be the date one day before the visit, the AE did no longer appear/ the grade had changed.

Example: The current visit date is 07.01.2019 the previous visit used to be 4 weeks ago at 10.12.2018 in between there used to be an AE but it is not clear when it actually started and ended. According the above rule the start date should be recorded as 11.12.2018 and the end date as 06.01.2019.

9. Query Management

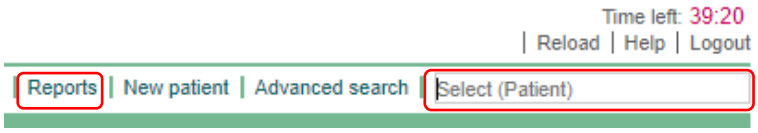
Whenever **data are missing, implausible or inconsistent** Data Management or the CRA will generate **queries** to clean them.

- A query will be allocated to the data field in question.
- Queried data are expected to be provided or corrected on base of the source data.
- If the queried data cannot be improved, the query answer should reflect this by confirming the data within the query reply together with an explanatory comment.

To avoid queries regarding data, that ultimately cannot be provided as requested, a **comment can be written directly at the end of the form**, confirming the data and providing an explanatory comment why the data are insufficient or missing. **This option is only possible on forms offering a Comment field on the bottom of the page.**

9.1 How to find queries

There are two ways of finding queries:



Forms containing queries are marked by a red triangle with a question mark. 

In more recent trials you might see also files marked with a 'D'. 

This label is used by SAKK to mark protocol deviations and does not require CRC attention.

1. You can directly look for query signs
   - Within a specific patient's visit plan / Casenode by typing it's UPN into the sT **'Select (Patient)' field** or

- By choosing an overview of all of your patients via 'Reports', opening report: **1.0 'Patient overview'**.

2. A second way to find queries is to open report: **2.0 'Query report'**.

This report provides you with all queries ever sent for your patients.

You can filter the report according to the query status:

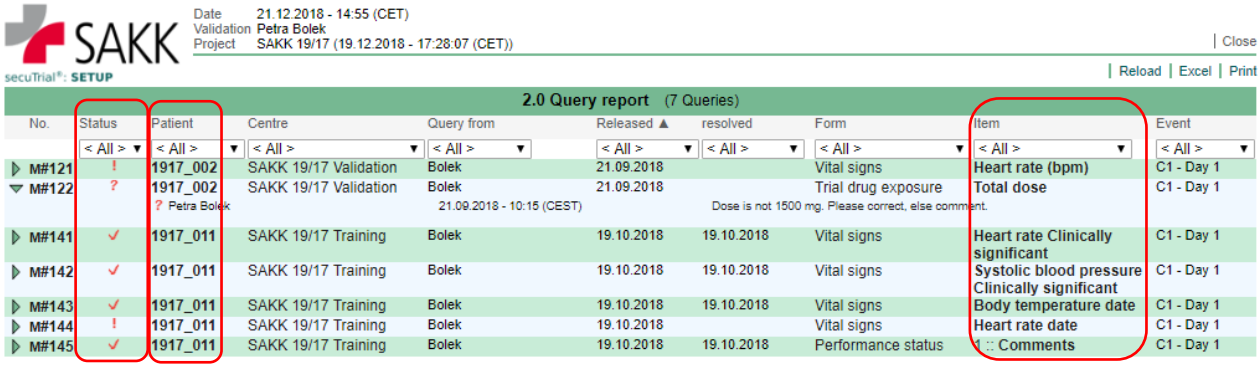
? = Query open- needs your attention

! = Query answered but not resolved by Data Management or CRA yet

√ = Query answered and resolved by Data Management or CRA

Using the report, you easily get an overview of what was already done and what still needs your attention.

Using the report is quite handy as it directly opens the respective form, a query is allocated to by clicking on the respective '**Item'**. Clicking the '**Patient'** number only opens the respective patient.


SAKK
secuTrial®: SETUP

Date 21.12.2018 - 14:55 (CET)
Validation Petra Bolek
Project SAKK 19/17 (19.12.2018 - 17:28:07 (CET))

Close | Reload | Excel | Print

2.0 Query report (7 Queries)

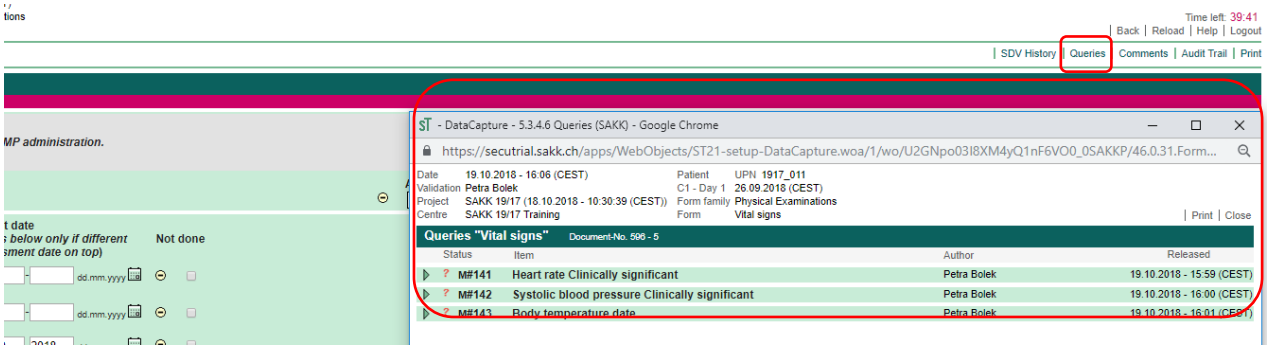
No.	Status	Patient	Centre	Query from	Released ▲	resolved	Form	Item	Event
	< All >	< All >	< All >	< All >	< All >	< All >	< All >	< All >	< All >
M#121	!	1917_002	SAKK 19/17 Validation	Bolek	21.09.2018		Vital signs	Heart rate (bpm)	C1 - Day 1
M#122	?	1917_002	SAKK 19/17 Validation	Bolek	21.09.2018		Trial drug exposure	Total dose	C1 - Day 1
		? Petra Bolek		21.09.2018 - 10:15 (CEST)			Dose is not 1500 mg. Please correct, else comment.		
M#141	√	1917_011	SAKK 19/17 Training	Bolek	19.10.2018	19.10.2018	Vital signs	Heart rate Clinically significant	C1 - Day 1
M#142	√	1917_011	SAKK 19/17 Training	Bolek	19.10.2018	19.10.2018	Vital signs	Systolic blood pressure Clinically significant	C1 - Day 1
M#143	√	1917_011	SAKK 19/17 Training	Bolek	19.10.2018	19.10.2018	Vital signs	Body temperature date	C1 - Day 1
M#144	!	1917_011	SAKK 19/17 Training	Bolek	19.10.2018		Vital signs	Heart rate date	C1 - Day 1
M#145	√	1917_011	SAKK 19/17 Training	Bolek	19.10.2018	19.10.2018	Performance status	1 :: Comments	C1 - Day 1

9.2 Query resolution

After identifying open queries, open the respective form (by going directly there or clicking on a query within '2.0 Query report').

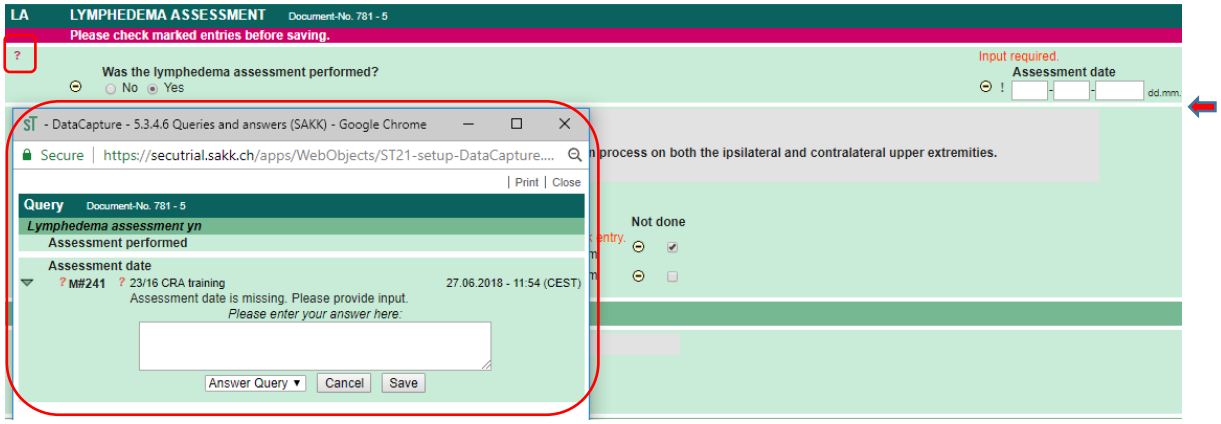
Now there are two ways to work on a query:

1) Either open a query listing for this form by using the '**Query'** button on top of the form at the right hand site **or**



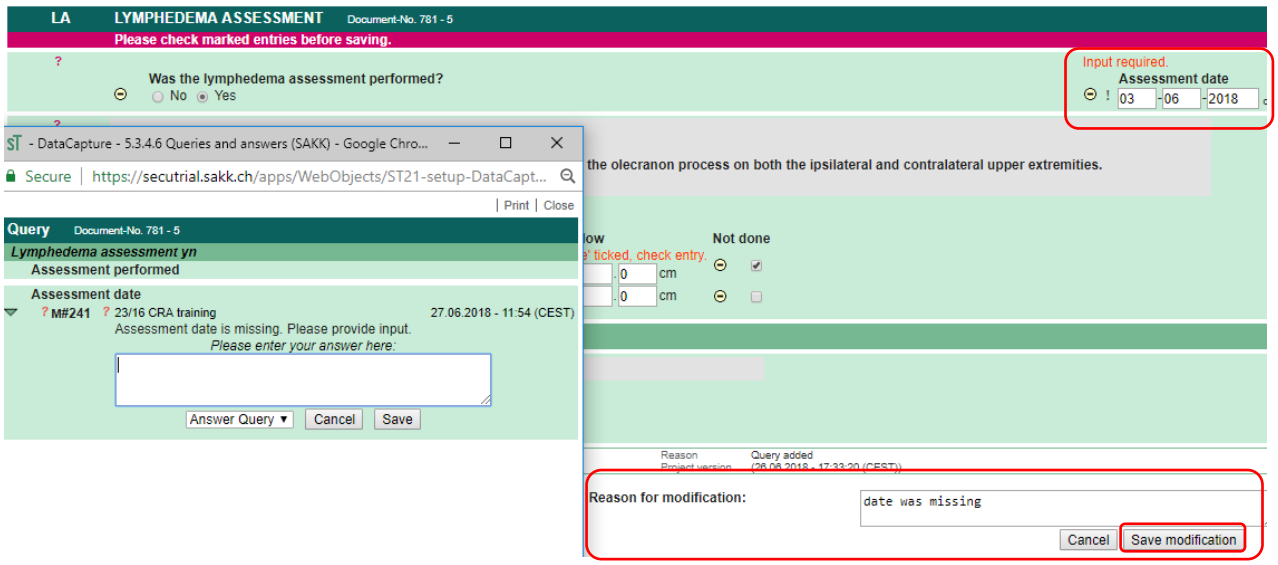
2) Look for red question marks (in newer trials a Q?) within the form.

Clicking on such a (Q) question mark will open a pop up window with details regarding all queries available within the respective section, in which the question mark is positioned (usually a white line separates sections. See arrow).



Whatever you prefer to do, go on by

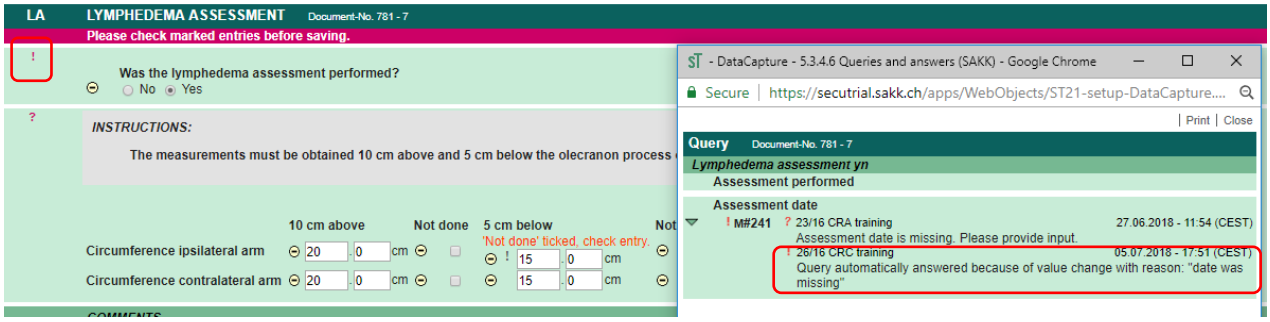
1. Reading the information regarding the queries to **understand the issues**.
2. Then **fill in the correct data** directly into the respective data fields **on the form!**
3. **Provide the reason for modification at the bottom of the form**. Here you can add additional explanations to Data Management also.
4. **Save the modification**!
5. Be aware that sometimes (**in case of open warnings**) you need to **click 'Save modification' a second time** (see section 7.5)!



6. After saving the modification, the question marks on the form and in the query listing should have been replaced by (Q) exclamation marks.

   The data you have recorded are saved on the form and the queries in the listing / the pop up with the query details are automatically populated with your answer provided in the 'Reason for modification' window.

   You can do more than one update within the form at once. Only one reason for modification and one time saving the modification will be necessary.



7. **Please note: the automatic answering of queries after data correction does not work in all cases**. Sometimes only the data changes will be saved but the query itself need to be closed manually, indicated by a remaining red question mark.

   If this happens **answer the query manually within the query pop up window / listing** by populating the "Please enter your answer here:" field and press the Save button.

   The "Please enter your answer here:" field becomes visible after expanding it using the little triangle on the left hand side for the pop up window or the pen on the right hand side for the query listing.

8. **Whenever you wish to provide an answer to a query but do not want to change the underlying data** e.g. you want to confirm queried data or data need to be changed elsewhere but not in the section of the form the query is attached to, manually answer the query as described above. Provide explaining information in the 'Please enter your answer here:' area.

9. **The section to which a query is attached, stays modifiable** as long as the answered query has not been finally resolved by the Data Manager or the CRA, indicated by a yellow icon with exclamation mark on the outside of the form.

open query

answered query

resolved query

Query resolution on former hidden sections

Query resolution on former hidden sections needs a two-step approach.

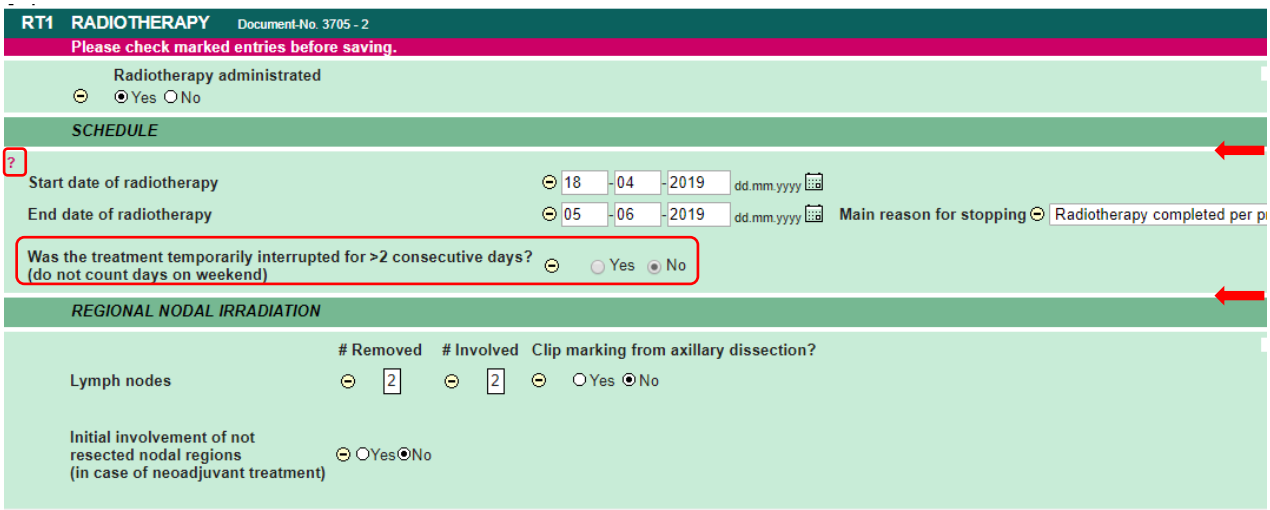
Often data fields or entire sections are hidden in sT until they are needed.

If data fields are hidden in a separate section (separated by white lines) and a query answer unhides this section, it is not possible to populate the now available data fields, although warnings like 'input required' do appear.

Therefore, in a first step the query needs to be answered. That expands the former hidden section (Query resolution needs to be saved 2x as there are now warnings in the expanded section).

In a second step, Data Management needs to put a query on the now visible section. Then with help of the new query the section can be populated.

Please see below pictures. The red arrows mark the section(s).



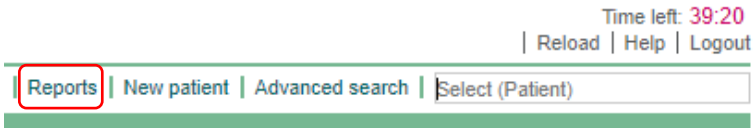
The answer to the query corrects 'Was the treatment interrupted for >2 consecutive days?' from 'No' to 'Yes'. This expands a former hidden section:

Now you have to wait for DM to set queries on the expanded section.

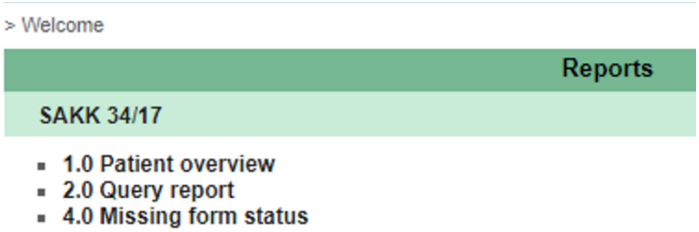
(All this is, as already explained, as soon as forms are SDVed or at least one query was set on the form, data can only be modified per section by a (not yet closed) query available in the respective section).

10. Reports

All reports are accessible from the sT 'Welcome' page by clicking on '**Reports'** on the upper right hand site of the page.



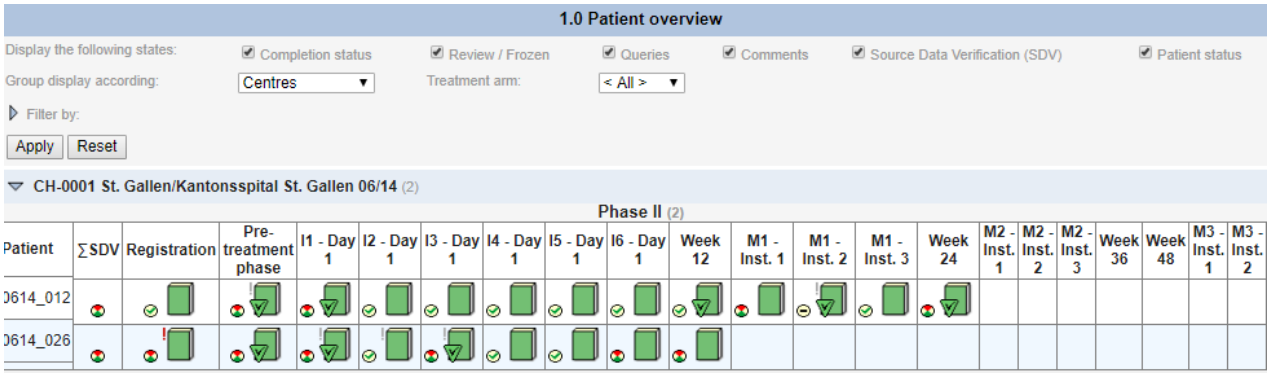
Reports available for your trial are listed similar to the below:



A minimum set of reports available are:

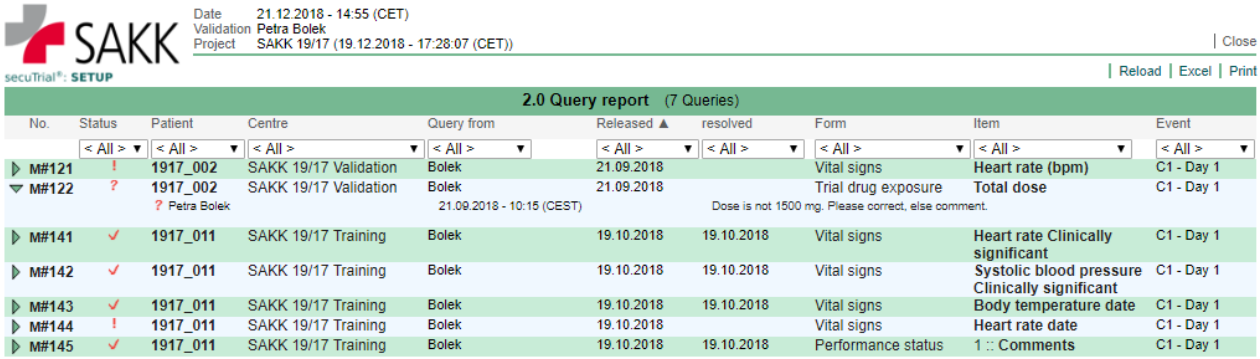
1.0 Patient overview, 2.0 Query report and 4.0 Missing form status

1.0 Patient overview



- The report provides a summary of all forms and their status for your patients.
- To choose one patient click on the Patient number on the left hand side.
- The level of details shown can be adapted via the check boxes on top of the page.
- Explanations regarding the icons shown can be found via 'Help' option on level of a Patient's Overview. (See section 5)

2.0 Query report



This report offers an overview of all open, answered and resolved queries

? = Query open- needs your attention

! = Query answered but not resolved by Data Management yet

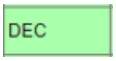
√ = Query answered and resolved by Data Management

See also section 9. Query Management

4.0 Missing form status

Patient	Pre-registration	Eligibility	Randomization	Baseline	SG - Week 1	SG - Week 4	Start of radiotherapy	End of treatment	Surgical procedures	Radiotherapy	Systemic treatment	Pathology	RT-QA	PRF	PI	Adverse Events
2316_0002	DEC	DEC	DEC	DEC	DEC	DEC			DEC	DEC	Form to complete	Empty form	DEC	Empty form	Empty form	
2316_0004	DEC	DEC	DEC	DEC	DEC	DEC	Empty form	DEC	DEC	DEC	Form to complete	Empty form	Empty form	Empty form	Empty form	
2316_0005	DEC	DEC	DEC	DEC	DEC	DEC			DEC	DEC	Form to complete	Empty form	DEC	Empty form	Empty form	
2316_0006	DEC	DEC	DEC	DEC	DEC	DEC			DEC	Empty form	Form to complete	Empty form	Empty form	Empty form	Empty form	
2316_0008	DEC	DEC	DEC	DEC	DEC	DEC			DEC	DEC	Empty form	Empty form	DEC	Empty form	Empty form	
2316_0017	DEC	DEC	DEC	DEC	DEC	DEC			DEC	Empty form	Empty form	Empty form	Empty form	Empty form	Empty form	
2316_0026	DEC	DEC	DEC	DEC	DEC				Form to complete	Empty form	Empty form	Empty form	Empty form	Empty form	Empty form	

This report offers an overview of all forms and their status respective all of your patients

- DEC = form is saved and closed 

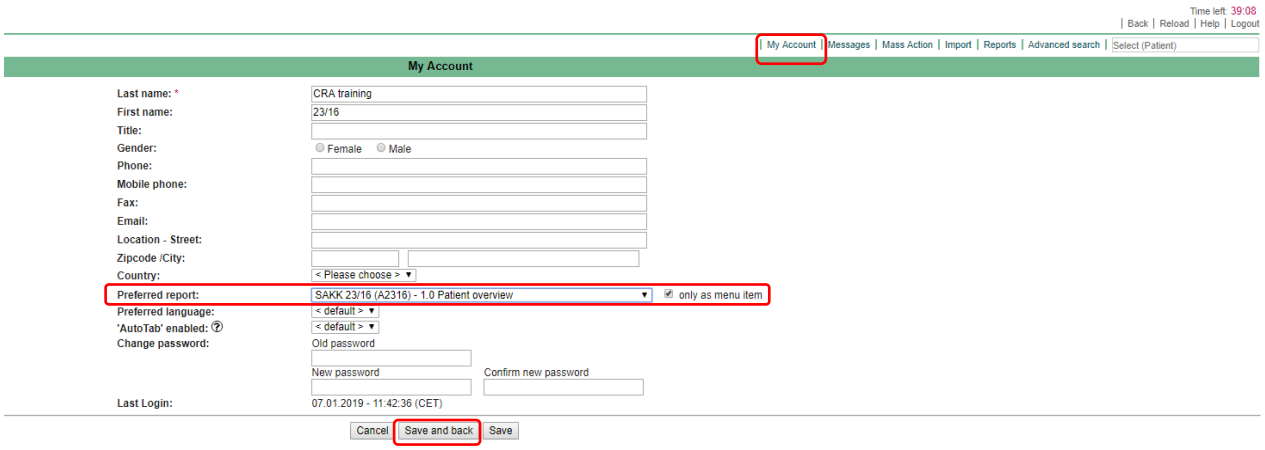
- Empty form = form is available but blank and not closed
- Form to complete = data are filled in but form not yet closed
- Blank field = form not created

Predefine most frequent used report for easy accessibility

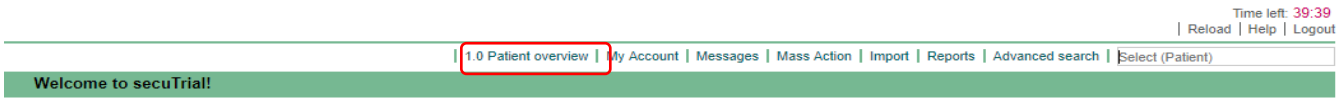
The report used most frequently can already be added to the top right side menu for easy accessibility. Example: Add 1.0 Patient Overview

Choose on the Welcome page **'My Account'**. An overview with all your personal data will pop up.

Under **'Preferred report'** choose the correct report and leave the pop up using button **'Save and back'**.



The chosen report is now part of the menu.



11. Guidelines, Training & Support

- For each trial a **Trial Specific Manual (TSM)**, which provides comprehensive instruction on how data have to be recorded, can be downloaded from the sT Welcome page (Download area).
- The **General User Manual** is stored on the sT '**Welcome**' page as well as on the **SAKK website**.
- The sT tool as well as eCRFs do have '**Help' buttons**. By clicking them additional information will become visible.
- Additional support can be requested from the SAKK CC (via the responsible CPM or CRA) regarding wrong warnings, false registered patients, login failure, training requests and any other support needed.

12. Document History

Version	Approval Date	Section	Brief description	Initials
1.0	07.11.2013	All	Initial version	SC
2.0	21.02.2019	All	Entirely revised version	PEB
2.1	01.04.2019	3	sT link updated	PEB
2.2	28.01.2020	7.4 9.2 9.1	Comment Section updated Query resolution on former hidden sections added New Query and Deviation signs	PEB
2.3	04.03.2020	3 7.4	New sT password rules Laboratory data- recording upper/ lower limits (ULN/LLN)	PEB