

# 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.

For document history information, please go to last page of this document!

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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
eSAE	Electronic Serious Adverse Event (form)
GUM	General User Manual
PI	Principal Investigator
SAE	Serious Adverse Event
SAKK	Swiss Oncology Research Network
SAKK CC	Swiss Oncology Research Network Coordination Center
SF	Screening Failure
SI	Sub investigator
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.



---

### SETUP

	choose a module:	directly go to customer SAKK:
 secuTrial®: <b>SETUP</b>	CustomerAdminTool	
	AdminTool	AdminTool (SAKK)
	FormBuilder	FormBuilder (SAKK)
	DataCapture	DataCapture (SAKK)
	ExportSearchTool	ExportSearchTool (SAKK)

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### PRODUCTIVE

	choose a module:	directly go to customer SAKK:
 The Swiss Oncology Research Network	AdminTool	AdminTool (SAKK)
	DataCapture	DataCapture (SAKK)
	ExportSearchTool	ExportSearchTool (SAKK)

### 3. Access to secuTrial

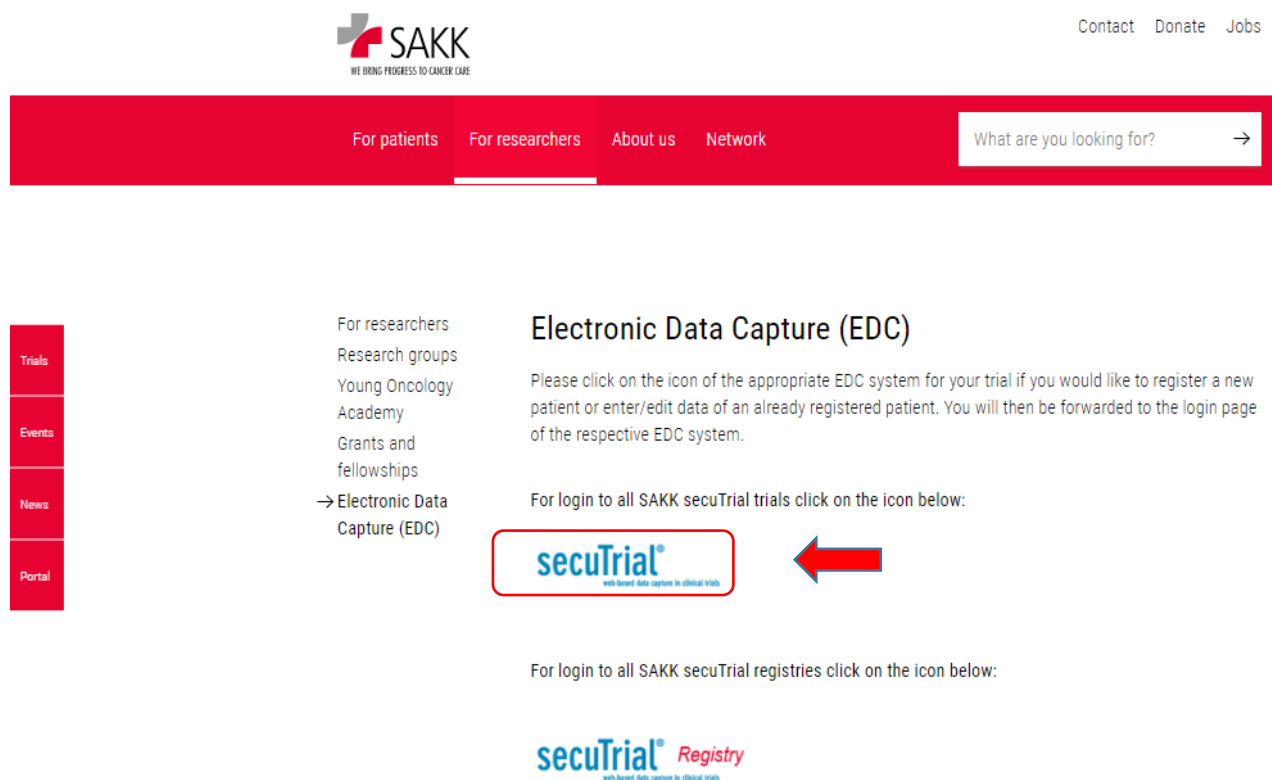
In order to receive authorization for online pre-registration, registration and data entry, sites have to send a copy of the completed staff list as well as the sT training log copy (for general and trial specific sT training) to the SAKK CC.

Subsequently, sT login credentials (user-ID and password) will be sent 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](http://www.sakk.ch/edc) by clicking on the secuTrial icon.



The screenshot shows the SAKK website header with the logo and navigation links: Contact, Donate, Jobs. Below the header is a red navigation bar with links for patients, researchers, about us, and network, along with a search bar. The main content area features a sidebar with links for Trials, Events, News, and Portal. The main content is titled "Electronic Data Capture (EDC)" and includes instructions on how to register a new patient or enter/edit data. It also provides a link to login to all SAKK secuTrial trials, with a red arrow pointing to the secuTrial logo. Below this, there is a link to login to all SAKK secuTrial registries, with a red arrow pointing to the secuTrial Registry logo.

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

This will lead to the following login mask:



Schweizerische Arbeitsgemeinschaft für Klinische Krebsforschung  
Groupe Suisse de Recherche Clinique sur le Cancer  
Swiss Group for Clinical Cancer Research  
Gruppo Svizzero di Ricerca Clinica sul Cancro  
**The Swiss Oncology Research Network**

**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](http://www.sakk.ch)

User-ID

Password

secuTrial® 5.3.4.6, 2018

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

Press the button 'Change password' and follow the instructions.

*The password has to consist of at least 8 characters and a minimum of 3 from the following characters have to be used:*

- Upper case letter (ABC)
- Lower case letter (abc)
- Number (1, 2, 3)
- 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 (aAa)
- Three or more consecutive numbers being directly successive (456)
- Five or more consecutive letters being directly alphabetically successive (aBcdE)

*Context related triviality is tested as well, forbidden 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 the button 'Password lost' and follow the instructions.

*Please note:*

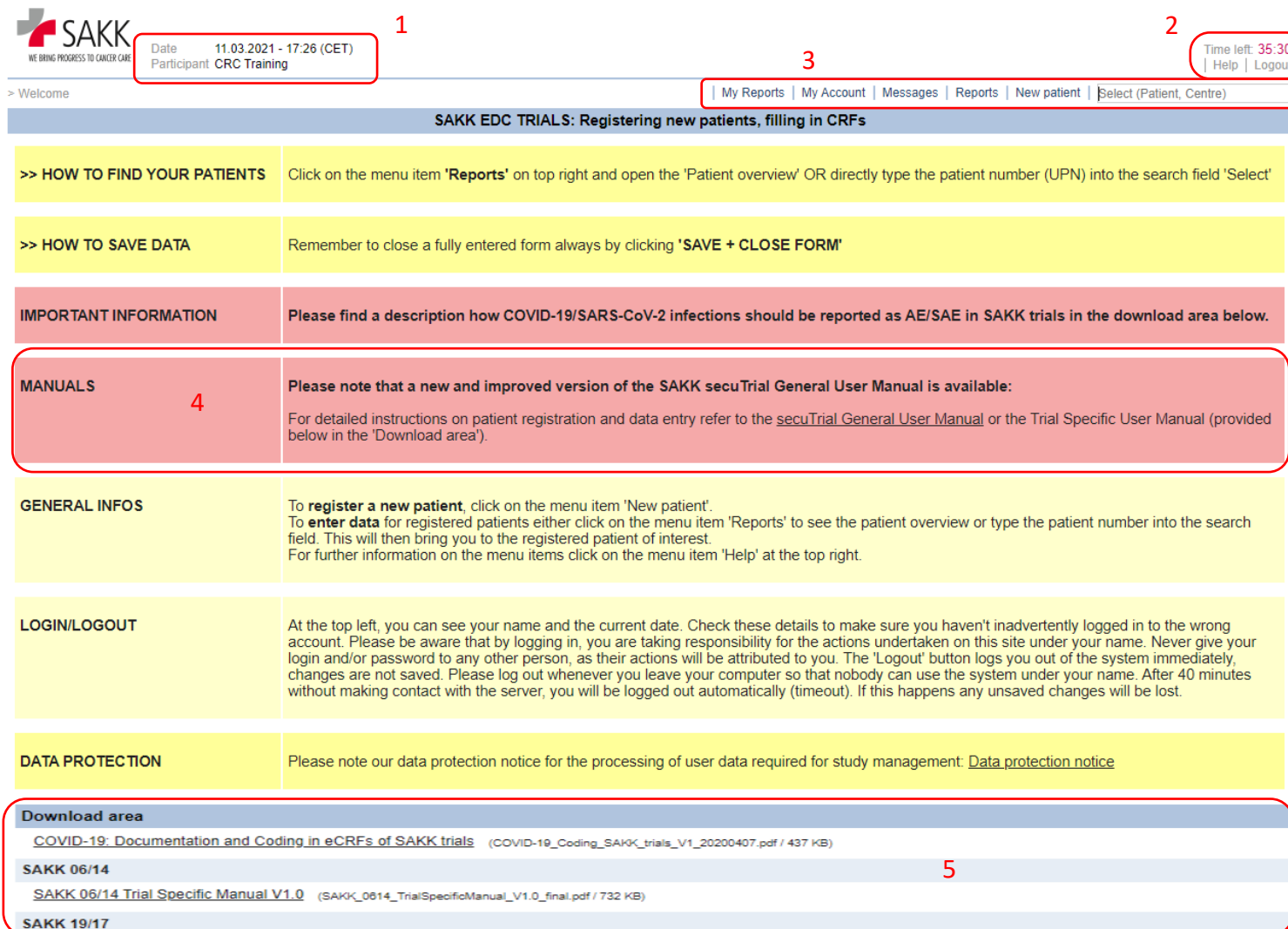
- *A person's login details for the same function e.g. CRC, CRA, etc. are identical across all SAKK sT trials.*
- *The usual format of a user-ID is: last name + first letter of first name*
- *Each trial requires a separate staff list to provide staff member with access rights.*
- *Staff lists have to 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 logging in, you are prompted to the 'Welcome page':



### 3.1 The 'Welcome page' and its functions

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



The screenshot shows the SAKK EDC TRIALS interface. At the top left is the SAKK logo. A box labeled '1' contains the user's name 'Participant CRC Training' and the date '11.03.2021 - 17:26 (CET)'. At the top right, a box labeled '2' contains 'Time left: 35:30' and 'Help | Logout' links. A navigation bar labeled '3' contains links: 'My Reports | My Account | Messages | Reports | New patient | Select (Patient, Centre)'. Below this is a blue header: 'SAKK EDC TRIALS: Registering new patients, filling in CRFs'. The main content area consists of several 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'
- 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** (highlighted with box '4'): 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](#)

At the bottom, a 'Download area' box (highlighted with box '5') contains the following links:

- [COVID-19: Documentation and Coding in eCRFs of SAKK trials](#) (COVID-19\_Coding\_SAKK\_trials\_V1\_20200407.pdf / 437 KB)
- SAKK 06/14**
- [SAKK 06/14 Trial Specific Manual V1.0](#) (SAKK\_0614\_TrialSpecificManual\_V1.0\_final.pdf / 732 KB)
- SAKK 19/17**

## 1. User information

Here you can see your name and the current date. Check these details to make sure you have not 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 functions within the taskbar.

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

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

The most important functions are:

**The 'Select (Patient, Centre)' 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. 1917\_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).

**'My Reports'** - here a list of reports can be displayed for quick access, determined by yourself on the Reports page. This button becomes only visible after you have added at least one 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

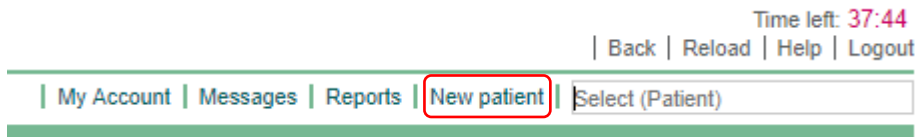
Here you find all **'Trial Specific Manuals' (TSM)** for trials you have access to.

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

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

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

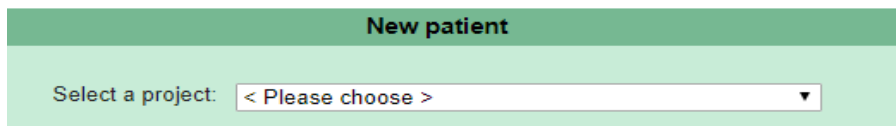
*Click in the sT taskbar 'New Patient'*



Time left: 37:44  
| Back | Reload | Help | Logout

| My Account | Messages | Reports | **New patient** | Select (Patient)

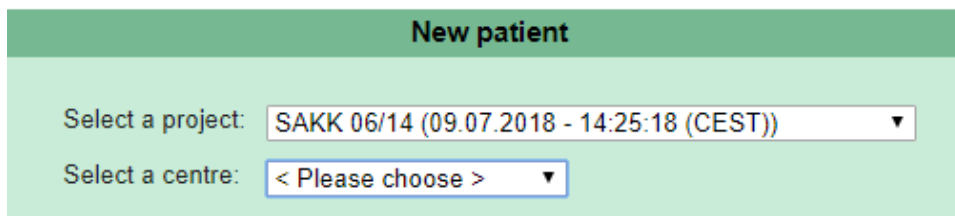
*Select the project (trial number) from the drop down menu:*



**New patient**

Select a project: < Please choose >

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

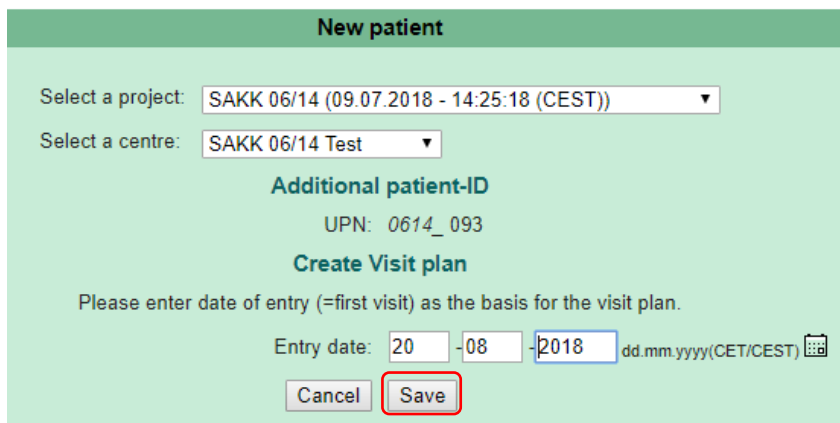


**New patient**

Select a project: SAKK 06/14 (09.07.2018 - 14:25:18 (CEST))

Select a centre: < Please choose >

*The window will expand to the following:*



**New patient**

Select a project: SAKK 06/14 (09.07.2018 - 14:25:18 (CEST))

Select a centre: SAKK 06/14 Test

**Additional patient-ID**  
UPN: 0614\_093

**Create Visit plan**  
Please enter date of entry (=first visit) as the basis for the visit plan.

Entry date: 20 -08 -2018 dd.mm.yyyy(CEST/CEST) 📅

Cancel Save

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

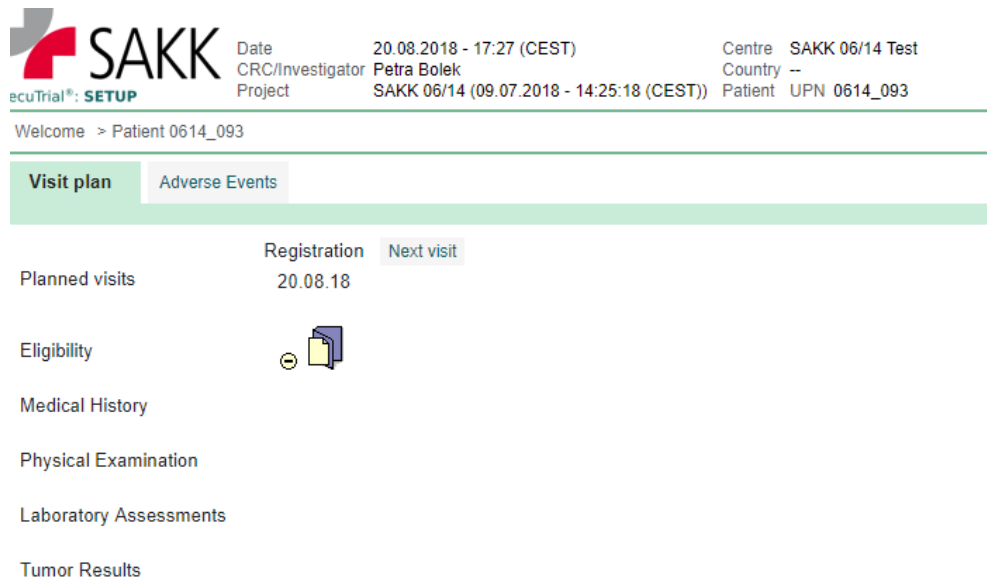
Usually you can find an information on how to define the 'Entry date'. Follow up accordingly.

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 ('Pre-)Registration' visit forms.



The screenshot shows the SAKK patient setup interface. At the top left is the SAKK logo and 'ecuTrial®: SETUP'. To the right, patient information is displayed in a table:

Date	20.08.2018 - 17:27 (CEST)	Centre	SAKK 06/14 Test
CRC/Investigator	Petra Bolek	Country	--
Project	SAKK 06/14 (09.07.2018 - 14:25:18 (CEST))	Patient	UPN 0614_093

Below the table, the breadcrumb 'Welcome > Patient 0614\_093' is visible. A green navigation bar contains 'Visit plan' (selected) and 'Adverse Events'. Under 'Visit plan', there are several sections: 'Planned visits' with a sub-section 'Registration' showing '20.08.18' and 'Next visit'; 'Eligibility' with a minus sign and document icon; 'Medical History'; 'Physical Examination'; 'Laboratory Assessments'; and 'Tumor Results'.

## 4.2 Register a patient

The registration files\* usually consists of 3 forms:

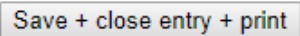
- ER Information on patient registration
- IE Inclusion / exclusion criteria
- EV Eligibility evaluations

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 require a previous completion of ERP, (IEP and EVP) form(s).

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

To do so, use the  button at the bottom of the page.

- *In recent trials an eligibility worksheet as defined in the trial protocol chapter 7 has 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.*
- *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 6.4). 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 to randomization, the 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](mailto: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 the 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 failure handling is the 'Trial Specific Manual' (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.

#### **4.5 Official 'Data Entry Correction' process for 'Hard Check' controlled data.**

This process mainly becomes necessary on registration forms. In case a patient was registered and/ or randomized and it turned out later the patient was actually not eligible, this has to be documented within the eCRF

- by changing the underlying data on the eligibility form and
- recording that the patient was actually not eligible and what in-/exclusion criteria had been violated.

As data on the registration forms are broadly protected by so called 'Hard Checks', this cannot be done by a normal correction process, as incorrect data on EV forms or the statement that a patient was not eligible will trigger the program to not allow saving the respective form(s).

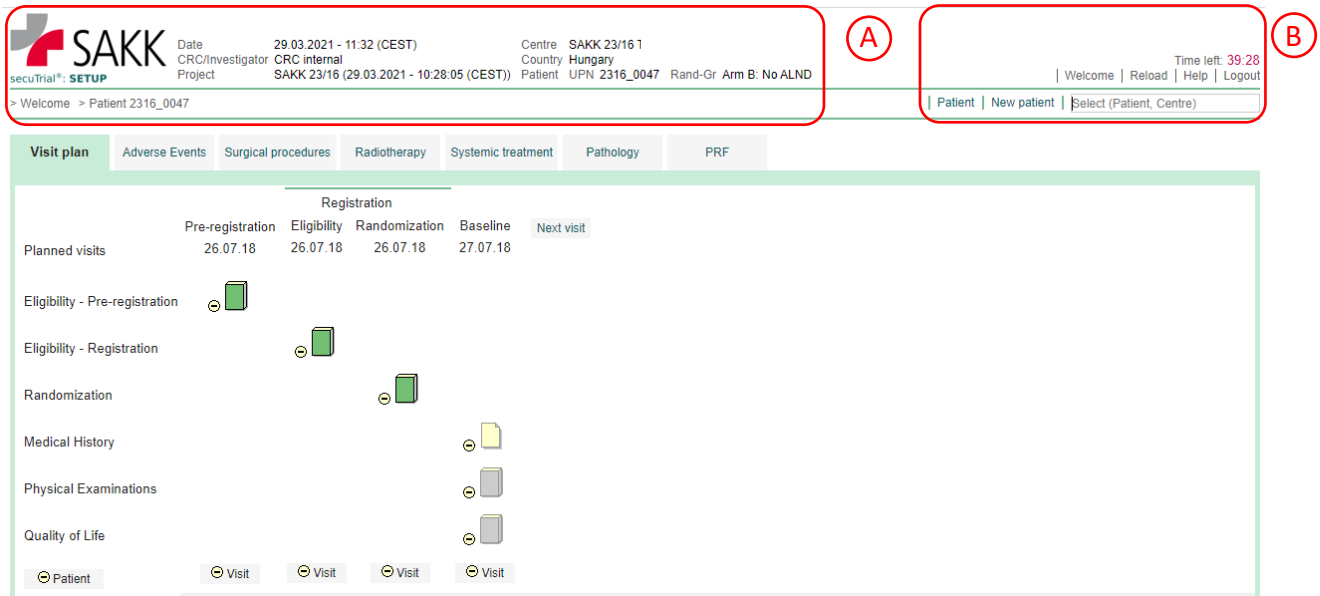
Please contact the trial CPM or CRA in case you get aware of this and you will be instructed on how to follow up.

In older trials, you will have to just confirm Queries and SAKK CC will correct the data for you.

In more recent trials you will be able to perform the correction yourself, after the CPM/CRA prompts you to do so.

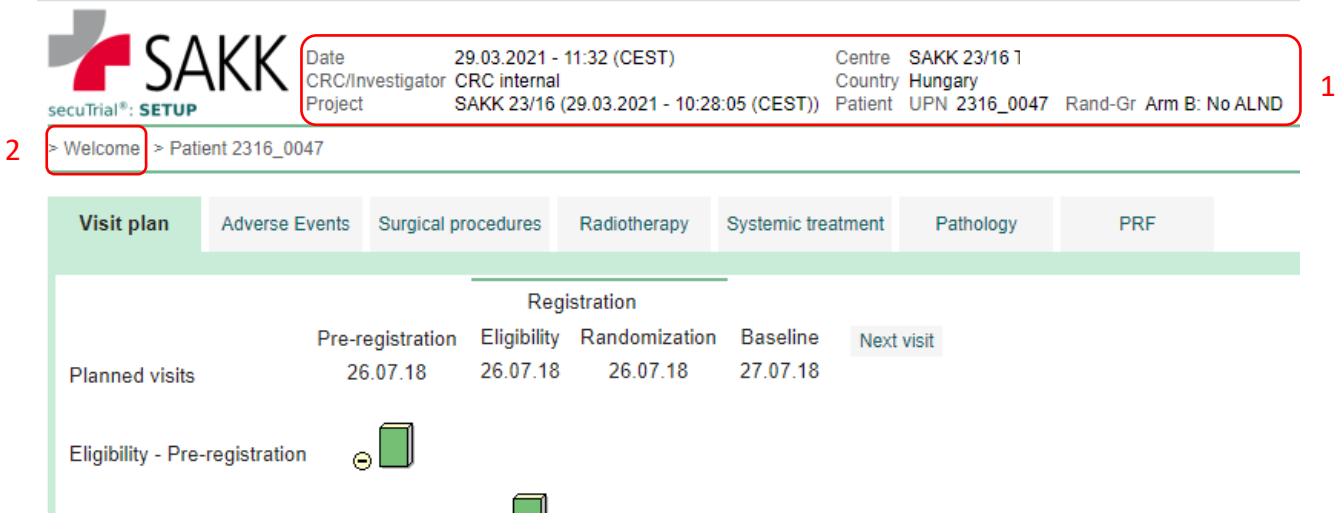
### 5. 'Form Overview'

After a new patient was successfully set-up, the system opens the patient's 'Form Overview' ('Visit plan' & 'Casenodes').



The screenshot shows the SAKK secuTrial interface. At the top, there is a header with the SAKK logo and patient information: Date 29.03.2021 - 11:32 (CEST), Centre SAKK 23/16 1, Country Hungary, CRC/Investigator CRC internal, Project SAKK 23/16 (29.03.2021 - 10:28:05 (CEST)), Patient UPN 2316\_0047, Rand-Gr Arm B: No ALND. A navigation bar below the header contains tabs: Visit plan, Adverse Events, Surgical procedures, Radiotherapy, Systemic treatment, Pathology, and PRF. The main content area displays a timeline for 'Registration' visits, including Pre-registration, Eligibility, Randomization, Baseline, and Next visit, with corresponding icons for each visit type.

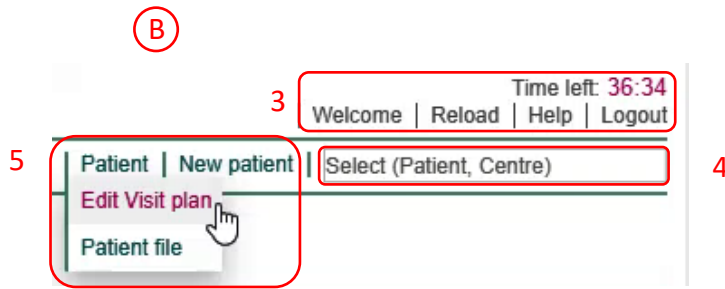
A



This screenshot is similar to the first one, showing the SAKK secuTrial interface. It includes the same header with patient information and navigation bar. Annotations are present: '1' points to the patient information header, and '2' points to the 'Welcome' button in the navigation bar. The main content area displays the 'Registration' timeline.

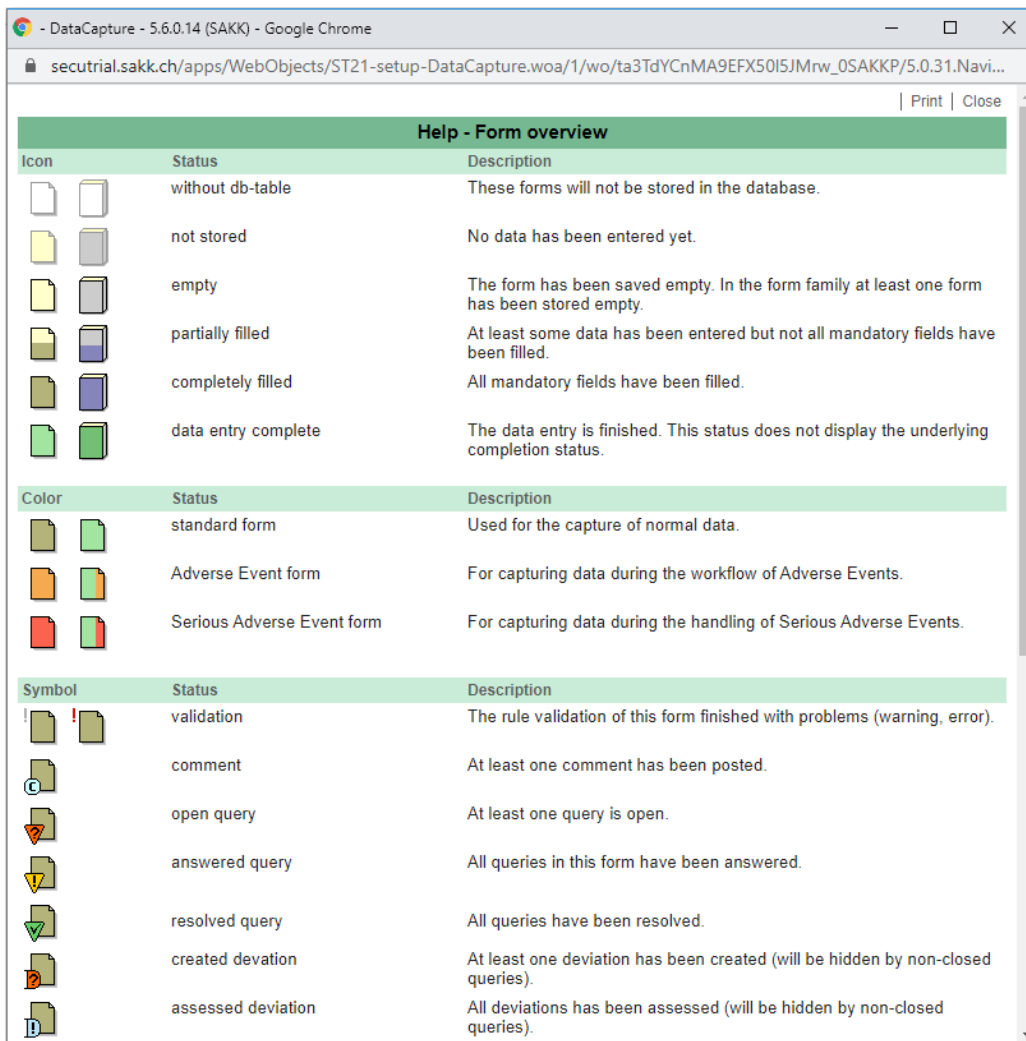
1. Important information regarding trial, patient, logged in person, etc.
2. Navigation option to the 'Welcome page'.





### 3.

- a. **'Time left'** – shows how much time is left until automatic log out
- b. Navigation option to 'Welcome page'
- c. **'Reload'** option to refresh the current page
- d. **'Logout'** option to leave sT in a safe manner
- e. **'Help'** option provides an overview of possible form status:



The screenshot shows a browser window titled 'DataCapture - 5.6.0.14 (SAKK) - Google Chrome'. The address bar shows the URL: `secutrial.sakk.ch/apps/WebObjects/ST21-setup-DataCapture.woa/1/wo/ta3TdYcNMA9EFX50I5JMrw_0SAKKP/5.0.31.Navi...`. The main content area displays a window titled 'Help - Form overview' with a 'Print | Close' button in the top right corner. The window contains a table with three columns: 'Icon', 'Status', and 'Description'.

Icon	Status	Description
	without db-table	These forms will not be stored in the database.
	not stored	No data has been entered yet.
	empty	The form has been saved empty. In the form family at least one form has been stored empty.
	partially filled	At least some data has been entered but not all mandatory fields have been filled.
	completely filled	All mandatory fields have been filled.
	data entry complete	The data entry is finished. This status does not display the underlying completion status.

Color	Status	Description
	standard form	Used for the capture of normal data.
	Adverse Event form	For capturing data during the workflow of Adverse Events.
	Serious Adverse Event form	For capturing data during the handling of Serious Adverse Events.

Symbol	Status	Description
	validation	The rule validation of this form finished with problems (warning, error).
	comment	At least one comment has been posted.
	open query	At least one query is open.
	answered query	All queries in this form have been answered.
	resolved query	All queries have been resolved.
	created deviation	At least one deviation has been created (will be hidden by non-closed queries).
	assessed deviation	All deviations has been assessed (will be hidden by non-closed queries).

#### 4. 'Select (Patient, Centre)': type in a UPN to get directly to that patient's 'Form Overview'.

*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 a few trials, there is also a site-specific documentation available. To get there type the USN instead of the UPN and choose the respective study number if more than one are available.

*The USN usually consists of a country identifier and the site number e.g.*

*CH-0001 Kantonsspital St. Gallen,*

*AT-0103 Tirol Kliniken- Landeskrankenhaus Innsbruck*

#### 5. 'Patient' and 'New patient'

- 'Patient'
  - I. Edit 'Visit plan' (for details, see section 6.1)
  - II. 'Patient file' to create a PDF or HTML file with all completed forms of your patient(s).
- 'New patient' (for details, see section 4.1)



The screenshot shows the SAKK secuTrial interface for a patient. At the top, the SAKK logo is on the left, and patient details are on the right: Date (29.03.2021 - 11:32 (CEST)), Centre (SAKK 23/16 Training Hungary), Country (Hungary), CRC/Investigator (CRC internal), Project (SAKK 23/16 (29.03.2021 - 10:28:05 (CEST))), Patient (UPN 2316\_0047), and Rand-Gr Arm B: No ALND. Below this, a breadcrumb trail reads '> Welcome > Patient 2316\_0047'. A navigation bar contains tabs: 'Visit plan' (highlighted with a red box and labeled '6'), 'Adverse Events', 'Surgical procedures', 'Radiotherapy', 'Systemic treatment', 'Pathology', and 'PRF' (highlighted with a red box and labeled '7'). Below the navigation bar, a 'Registration' section shows a timeline of visits: Pre-registration (26.07.18), Eligibility (26.07.18), Randomization (26.07.18), and Baseline (27.07.18). A 'Next visit' button (highlighted with a red box and labeled '8') is positioned to the right of the Baseline date. Below the timeline, there are expandable sections for 'Eligibility - Pre-registration' and another section, each with a minus sign and a document icon.

#### 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.

#### 7. Beside the 'Visit plan', there are 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).

#### 8. New visits will be created using the 'Next visit' button.

## 6. The 'Visit plan'

> Welcome > Patient 2316\_0047 > Baseline | Patient | New patient | Select (Patient, Centre)

**Visit plan** | Adverse Events | Surgical procedures | Radiotherapy | Systemic treatment | Pathology | PRF

	Pre-registration	Eligibility	Randomization	Baseline	SG - Week 1	SG - Week 4
Planned visits	26.07.18	26.07.18	26.07.18	27.07.18	28.07.18	18.08.18

Next visit **2**

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 Examination at Baseline visit)

5

Lymphedema assessment | Shoulder motion | Vital signs

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 based on the date a patient was created /registered in sT.

**Visit plan** | Adverse Events | Surgical procedures | Radiotherapy | Systemic treatment

	Pre-registration	Registration		
Planned visits	13.02.18	Eligibility 14.02.18	Randomization 15.02.18	Baseline 16.02.18

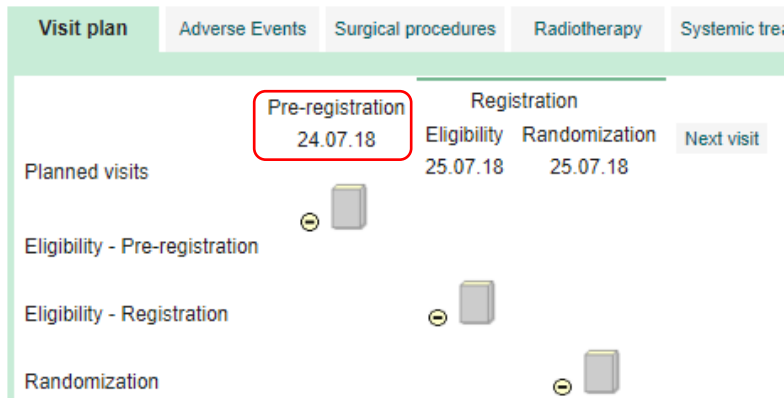
Eligibility - Pre-registration

Eligibility - Registration

- To use the 'Planned visit dates' as a helpful orientation during the course of the trial, they need 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 actually at a different date, than the scheduled one and the trial protocol allows a shift of future visits relatively to the registration date, the visit date can be adjusted. (See next section, 6.1 Edit 'Visit plan' dates)

### 6.1 Edit 'Visit plan' dates

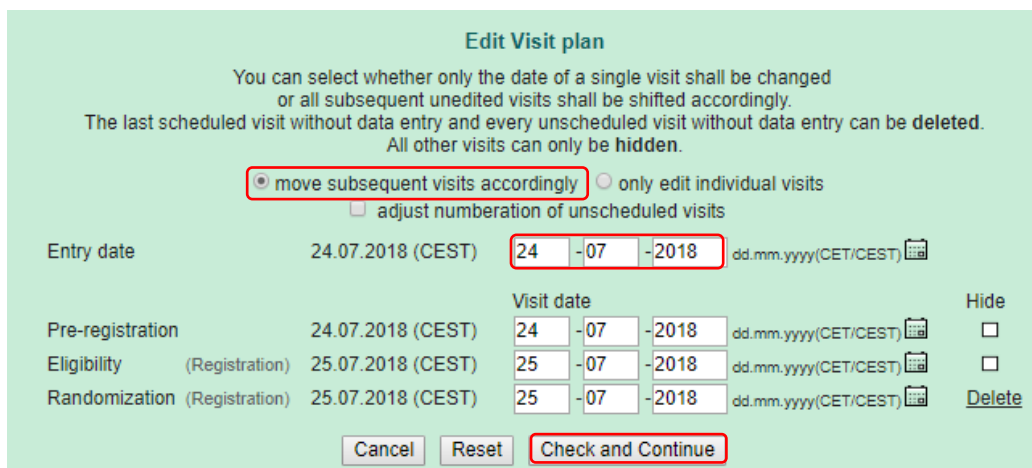
As an **example** we have the following situation – a patient was created on 24.07.18, hence the first visit here – 'Pre-registration' comes with the date 24.07.18. For some reason the 'Pre-registration' actually has taken place later on 25.07.18. Therefore, the entry date should be adjusted accordingly.



To do so, being on the patient's 'Form Overview' click on the right-hand side on the 'Patient' & 'Edit Visit plan' option.



The following window will appear:



**Edit Visit plan**

You can select whether only the date of a single visit shall be changed or all subsequent unedited visits shall be shifted accordingly. The last scheduled visit without data entry and every unscheduled visit without data entry can be deleted. All other visits can only be hidden.

move subsequent visits accordingly
  only edit individual visits

adjust numbering of unscheduled visits

Entry date	24.07.2018 (CEST)	24	-07	-2018	dd.mm.yyyy(CEST/CEST)	
Pre-registration	24.07.2018 (CEST)	24	-07	-2018	dd.mm.yyyy(CEST/CEST)	<input type="checkbox"/> Hide
Eligibility (Registration)	25.07.2018 (CEST)	25	-07	-2018	dd.mm.yyyy(CEST/CEST)	<input type="checkbox"/> Hide
Randomization (Registration)	25.07.2018 (CEST)	25	-07	-2018	dd.mm.yyyy(CEST/CEST)	<input type="checkbox"/> Delete

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 requires a reason for modification and can be saved, if all is correct.*

**Edit Visit plan**

You can select whether only the date of a single visit shall be changed or all subsequent unedited visits shall be shifted accordingly. The last scheduled visit without data entry and every unscheduled visit without data entry can be **deleted**. All other visits can only be **hidden**.

move subsequent visits accordingly  
  only edit individual visits  
 adjust number of unscheduled visits

<b>Current visit plan</b>		<b>New visit</b>	
Entry date	24.07.2018 (CEST)	Entry date	25.07.2018 (CEST)
Pre-registration	24.07.2018 (CEST)	Pre-registration	25.07.2018 (CEST)
Eligibility (Registration)	25.07.2018 (CEST)	Eligibility (Registration)	26.07.2018 (CEST)
Randomization (Registration)	25.07.2018 (CEST)	Randomization (Registration)	26.07.2018 (CEST)

Reason for modification:

Registration performed 1 day after patient set up

*Subsequently the 'Visit plan' will look like this:*

**Visit plan**   Adverse Events   Surgical procedures   Radiotherapy   Systemic tr

	Pre-registration		Registration		Next visit
	25.07.18		Eligibility	Randomization	
Planned visits					
Eligibility - Pre-registration	⊖	📄			
Eligibility - Registration			⊖	📄	
Randomization				⊖	📄

**Please note:**

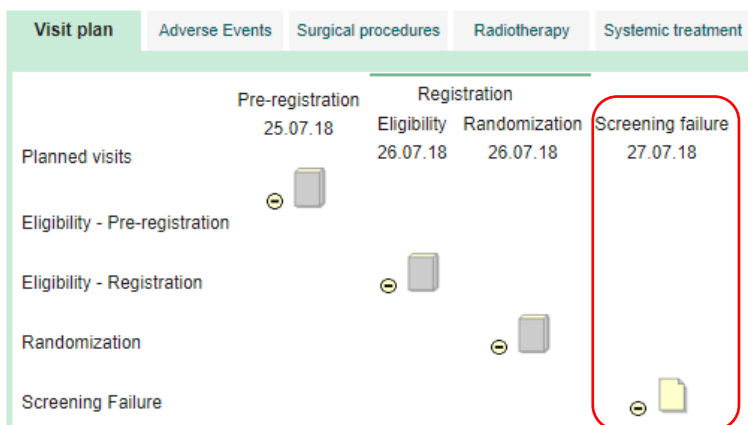
***A visit name or the order of scheduled visits cannot be corrected!***

*If you have recorded data within the wrong visit, you have to delete them from the respective forms and record them in the correct ones.*

### 6.2 Deleting visits

In case, a visit had been set up erroneously and none of the respective forms has been modified (*an opened form was always left by using the 'Cancel' button*), the respective visit can be deleted entirely.

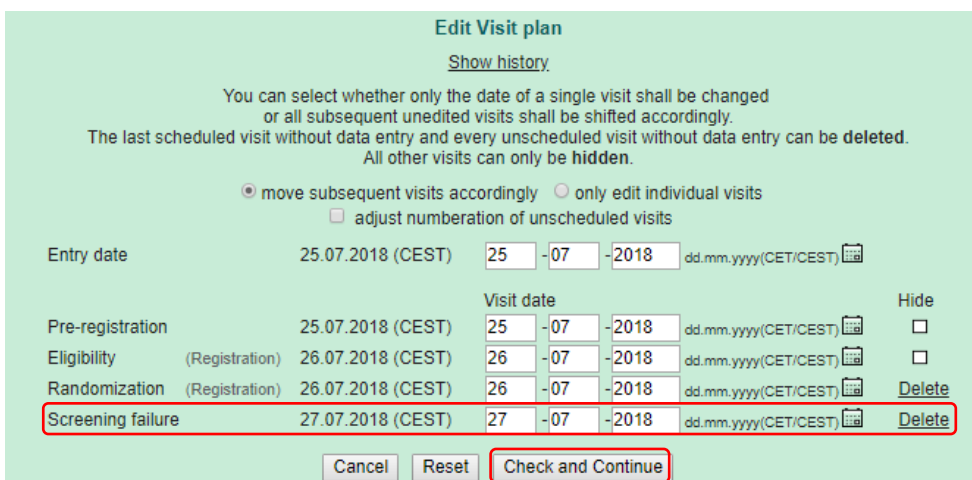
For **example**, a 'Screening failure' form (SF) was created accidentally and needs to be deleted.



Do so by clicking on the right-hand side 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 requires a reason for modification and can be **saved**, if all is correct.*

**Edit Visit plan**

[Show history](#)

You can select whether only the date of a single visit shall be changed or all subsequent unedited visits shall be shifted accordingly.  
The last scheduled visit without data entry and every unscheduled visit without data entry can be **deleted**.  
All other visits can only be **hidden**.

move subsequent visits accordingly   
  only edit individual visits  
 adjust numeration of unscheduled visits




Current visit plan		New visit	
Entry date	25.07.2018 (CEST)	Entry date	25.07.2018 (CEST)
Pre-registration	25.07.2018 (CEST)	Pre-registration	25.07.2018 (CEST)
Eligibility (Registration)	26.07.2018 (CEST)	Eligibility (Registration)	26.07.2018 (CEST)
Randomization (Registration)	26.07.2018 (CEST)	Randomization (Registration)	26.07.2018 (CEST)
Screening failure	27.07.2018 (CEST)		

Reason for modification:

SF created in error

*Subsequently the 'Visit plan' will no longer show the SF form:*

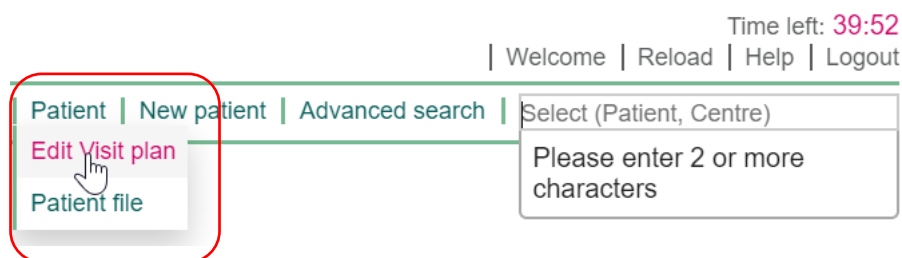
**Visit plan**    Adverse Events    Surgical procedures    Radiotherapy    Systemic tr

	Pre-registration 25.07.18	Registration		Next visit
		Eligibility 26.07.18	Randomization 26.07.18	
Planned visits				
Eligibility - Pre-registration	☹ 			
Eligibility - Registration		☹ 		
Randomization			☹ 	

### 6.3 Hide visits

For trials activated in 2021 or later, there will be the option available for CRCs to hide wrongfully created visits, whenever deletion is not possible anymore.

*In order to hide a visit, click on 'Patient' on the upper right-hand side of the patient's 'Form Overview'. Then, choose the option 'Edit Visit plan'.*



*Click on the 'Hide' box next to the visit that needs to be hidden. Save your modification by pressing 'Check and Continue'.*

#### Edit Visit plan

[Show history](#)

You can select whether only the date of a single visit shall be changed or all subsequent unedited visits shall be shifted accordingly.  
The last scheduled visit without data entry and every unscheduled visit without data entry can be **deleted**.  
All other visits can only be **hidden**.

move subsequent visits accordingly   
  only edit individual visits  
 adjust numbering of unscheduled visits

		Entry date	Visit date				
		30.09.2020 (CEST)	30	-09	-2020	dd.mm.yyyy(CET/CEST)	
Eligibility	(Registration)	01.10.2020 (CEST)	01	-10	-2020	dd.mm.yyyy(CET/CEST)	<b>Hide</b>
Baseline	(Registration)	02.10.2020 (CEST)	02	-10	-2020	dd.mm.yyyy(CET/CEST)	<input type="checkbox"/>
IND C1	(Induction phase (part 1))	03.10.2020 (CEST)	03	-10	-2020	dd.mm.yyyy(CET/CEST)	<input type="checkbox"/>
IND C2	(Induction phase (part 1))	24.10.2020 (CEST)	24	-10	-2020	dd.mm.yyyy(CET/CEST)	<input type="checkbox"/>
IND C3	(Induction phase (part 1))	14.11.2020 (CET)	14	-11	-2020	dd.mm.yyyy(CET/CEST)	<input type="checkbox"/>
IND C4	(Induction phase (part 1))	14.11.2020 (CET)	14	-11	-2020	dd.mm.yyyy(CET/CEST)	<input type="checkbox"/>
MAIN C5	(Maintenance phase (part 2))	05.12.2020 (CET)	05	-12	-2020	dd.mm.yyyy(CET/CEST)	<input type="checkbox"/>
MAIN C6	(Maintenance phase (part 2))	02.01.2021 (CET)	02	-01	-2021	dd.mm.yyyy(CET/CEST)	<b>Delete</b>
Tumor assessment		03.01.2021 (CET)	03	-01	-2021	dd.mm.yyyy(CET/CEST)	<input checked="" type="checkbox"/>

*You will be led to another window where you have to enter a reason and then click on 'save'.*



### Edit Visit plan

[Show history](#)

You can select whether only the date of a single visit shall be changed or all subsequent unedited visits shall be shifted accordingly.  
The last scheduled visit without data entry and every unscheduled visit without data entry can be **deleted**.  
All other visits can only be **hidden**.

move subsequent visits accordingly   
  only edit individual visits  
 adjust numbering of unscheduled visits

Current visit plan			New visit		
Entry date		30.09.2020 (CEST)	Entry date		30.09.2020 (CEST)
Eligibility	(Registration)	01.10.2020 (CEST)	Eligibility	(Registration)	01.10.2020 (CEST)
Baseline	(Registration)	02.10.2020 (CEST)	Baseline	(Registration)	02.10.2020 (CEST)
IND C1	(Induction phase (part 1))	03.10.2020 (CEST)	IND C1	(Induction phase (part 1))	03.10.2020 (CEST)
IND C2	(Induction phase (part 1))	24.10.2020 (CEST)	IND C2	(Induction phase (part 1))	24.10.2020 (CEST)
IND C3	(Induction phase (part 1))	14.11.2020 (CET)	IND C3	(Induction phase (part 1))	14.11.2020 (CET)
IND C4	(Induction phase (part 1))	14.11.2020 (CET)	IND C4	(Induction phase (part 1))	14.11.2020 (CET)
MAIN C5	(Maintenance phase (part 2))	05.12.2020 (CET)	MAIN C5	(Maintenance phase (part 2))	05.12.2020 (CET)
MAIN C6	(Maintenance phase (part 2))	02.01.2021 (CET)	MAIN C6	(Maintenance phase (part 2))	02.01.2021 (CET)
Tumor assessment		03.01.2021 (CET)	Tumor assessment		03.01.2021 (CET)

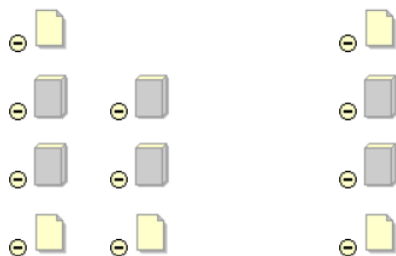
Reason for modification:

Visit created by mistake

On the patient's 'Visit plan', the hidden visit will be indicated by **three dots in square brackets**.

Maintenance phase (part 2)		Maintenance phase (part 2)	
MAIN C5	MAIN C6	[...]	MAIN C7
05.12.20	02.01.21		30.01.21

[Next visit](#)



By clicking on this placeholder, the visit expands and can be seen but not edited as indicated by the message in the form:

This form is in a visit which has been hidden. It cannot be edited anymore.

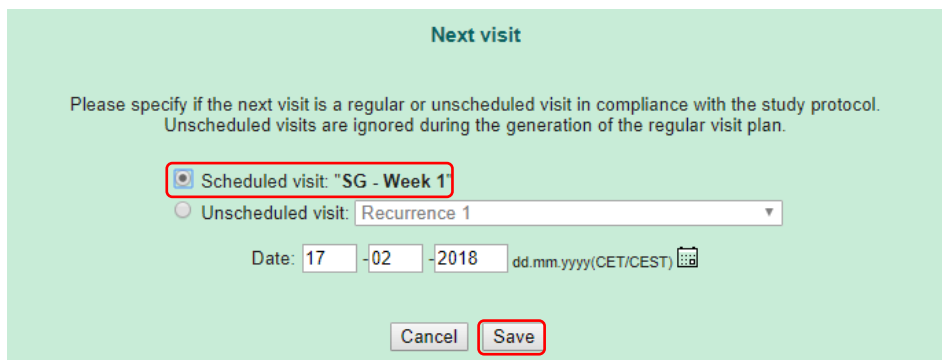
*In order to reverse the process and unhide the visit, use the same process as for hiding it previously: click on 'Edit Visit plan', remove the tick in the 'Hide' box, enter a reason and save it. The visit will be visible and editable again.*

Data recorded in the forms that are supposed to be hidden **do not need** to be deleted before hiding the visit, as this data will not be part of the statistical analysis or further validation. However, already existing **Queries must be answered and closed** before hiding the visit!

### 6.4 Adding scheduled visits

To add the next scheduled visit, press the **'Next visit'** button on the patient's 'Form 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 becomes available within the 'Visit plan'.

*As long as no data have been saved in the newly created visit (not even a blank 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](#)*



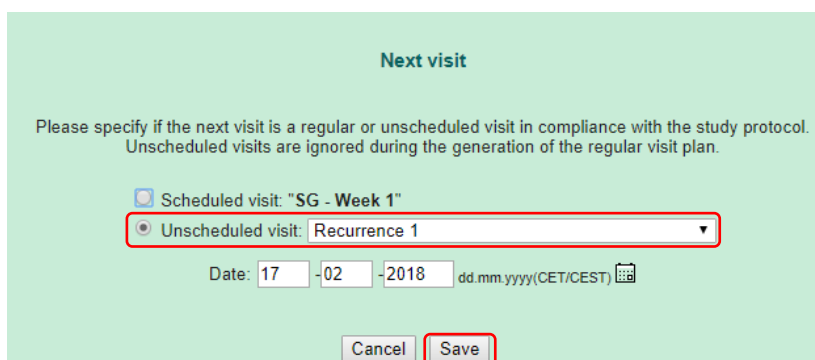
The screenshot shows a dialog box titled "Next visit" with a light green background. It contains the following elements:
 

- Text: "Please specify if the next visit is a regular or unscheduled visit in compliance with the study protocol. Unscheduled visits are ignored during the generation of the regular visit plan."
- Radio button selection: "Scheduled visit: SG - Week 1" is selected and highlighted with a red box. "Unscheduled visit: Recurrence 1" is unselected.
- Date field: "Date: 17 -02 -2018" with a calendar icon and the format "dd.mm.yyyy(CET/CEST)".
- Buttons: "Cancel" and "Save" (highlighted with a red box).

### 6.5 Adding unscheduled visits

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

Adjust the visit date if necessary and save data.



The screenshot shows the same "Next visit" dialog box as above, but with the following changes:
 

- Radio button selection: "Scheduled visit: SG - Week 1" is unselected. "Unscheduled visit: Recurrence 1" is selected and highlighted with a red box.
- Buttons: "Cancel" and "Save" (highlighted with a red box).

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

*As long as no data have been saved in the newly created visit (not even a blank 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*

## 7. Data Entry

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


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

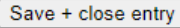
In these trials, the forms are only available on paper for site staff and need to be sent by email to SAKK CC.

For details, see trial protocol chapter 10 &11.



Paper forms sent to SAKK CC will be entered into sT 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.  -  -  (dd).(mm).yyyy 
- In older trials, the following convention is in place:  
Missing days have to be recorded as 15.mm yyyy. In case only the year is known, day and month should be recorded as 30.06.yyyy.*
- ❖ To document medication, use the **English GENERIC name**, not the brand name. (E.g. Anastrozole not Arimidex)
- ❖ Indicate **missing data or entire assessments** by ticking the respective '**Not Done**' box.
- ❖ **Implausible data** will trigger '**Warnings**' in red/orange color. To avoid queries, **do NOT ignore them**. Follow up immediately and provide / correct respective data before saving.
- ❖ Whenever data definitely cannot be recorded as requested and a 'Comments' field is available on the bottom of 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** that are available in a timely manner. 

*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.
- ❖ If an expected visit did not take place, **the visit must still be created**. Enter the due date from the scheduler as the planned visit date and tick `not done` or `not applicable` within the form. This is not necessary for treatment visits that would have taken place after a patient dropped out.
- ❖ **Delete accidentally created visits** before even saving one blank form (use the cancel button to leave the forms). **Accidentally created visits that were saved already**, cannot be deleted anymore. In this case, **hide the visit** unless you need it later. (see section: 6.3) Before hiding, make sure all Queries are resolved and closed. 
- ❖ **AE forms** that have been accidentally set up and saved or completed with data not needed, **can also be hidden** (see section [Hide AEs](#)). Before hiding, make sure Queries are all resolved and closed. 
- ❖ Double click a **radio button**  No  Yes you like to un-check.  No  Yes

## 7.2 How to access patient's data.

Patient's data recorded in sT can be accessed in three ways from the 'Welcome page':



1. Type the patient number (UPN) into the field '**Select (Patient, Centre)**' and press Enter. This opens directly the respective patient's 'Form Overview' ('Visit plan' & 'Casenodes')
2. Click '**Reports**' and open on the 'Reports' page report: '**1.0 Patient Overview**'.
3. Alternatively pick the report via '**My Reports**' if available.

On the report '**1.0 Patient Overview**' you get an overview of all patients belonging to your site and the status of their forms.


A click on the patient's UPN or any other icon belonging to the patient, opens the respective patient's 'Form Overview' ('Visit plan' & 'Casenodes')



To switch from one patient to another, use the **'Select (Patient, Center)'** option or use the **'1.0 Patient Overview'** report, which remains available until a new report will be opened.

### 7.3 How to access a patient's form

In the TSM all 'Form families' with their forms are listed in one table (section: 'Overview of available forms'). It provides an overview of where data required by the protocol can be recorded within 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 in 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:

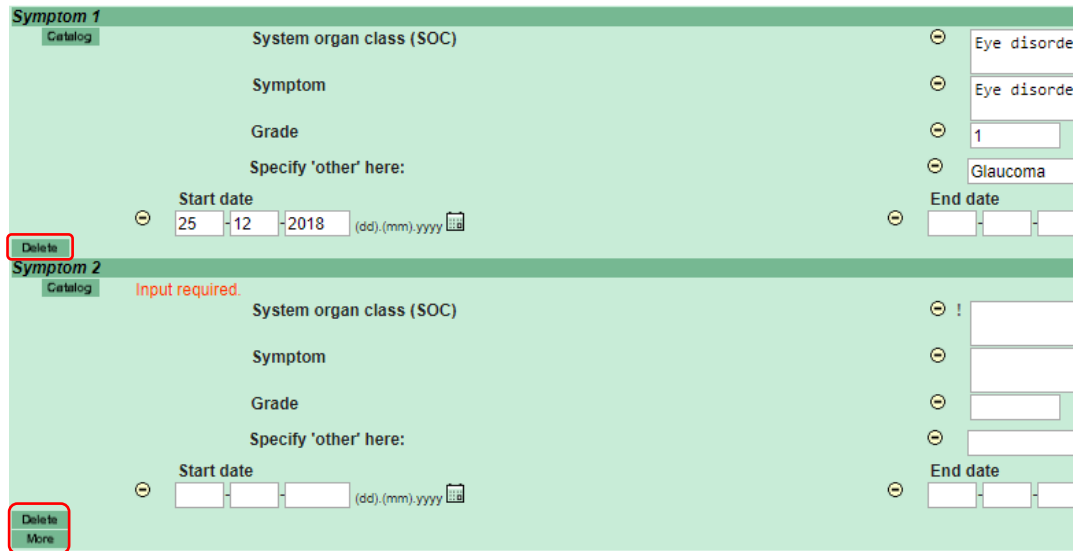
- *Missing days have to be recorded as 15.mm.yyyy In case only the year is known, day and month should be recorded as 30.06.yyyy.*

#### Add/ delete records - Repetition groups

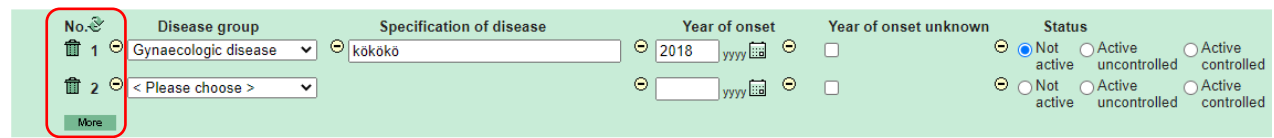
On some forms, e.g. AE, Concomitant Medication, Baseline Symptoms, etc. it is possible to add as many records as needed.

- *To do so click the **'More'** button on the left-hand side.*

- As long as data have not been Source Data Verified (SDVed) and no Query is allocated to the form, it is possible to delete the created record by clicking the **Delete** button or **trashcan icon** on the left-hand side.



or



### Scores

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

Lesion type	LDi	SDi
Node	15 mm	10 mm
Node	20 mm	15 mm
< Please choose >	mm	mm
< Please choose >	mm	mm
< Please choose >	mm	mm
< Please choose >	mm	mm
Sum of length x width of target lesions	Score 450 mm <sup>2</sup>	

### Missing data

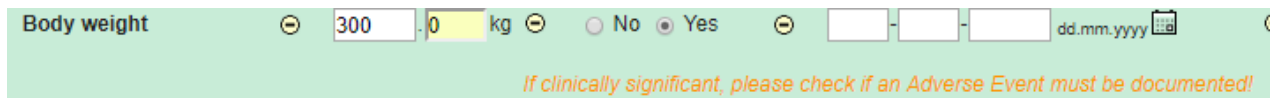
Missing data can usually be indicated as such (exceptions are the Eligibility and Randomization forms).

- 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’, ‘Unknown’, ‘NA’, etc.** if other values on the same form can be provided.

- *If there is no such option, the requested data should be provided whenever possible. If 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 laboratory values: ‘If clinically significant, please check if an Adverse Event must be documented!’



- *Please note that these messages will remain on the form, even if the requested task is fulfilled.*

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

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

- *ULL/LLN values have to be recorded once in the beginning of a trial.*
- *When the following lab form will be opened (without being saved previously), ULL/LLN values will be transferred.*
- *Please check ULL/LLN values for correctness and completeness and update them if necessary. Finally, confirm their correctness using the respective box in the last section of the Lab form.*

I confirm the correctness of all LLN and ULN values present in this form

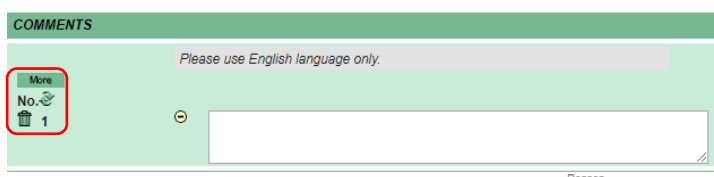
- *As the ULL/LLN data are only copied from the previous lab form, they will be missing if the previous lab has not been performed or single values are missing.*

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

*Please complete /correct ULN/LLN values before completing & saving any following lab visit, as data will be transferred only when opening a fresh lab form (previously not saved); otherwise, you have to complete data manually for more than one visit!*

**Comment Section**

The majority of forms contain a comment section on the bottom.



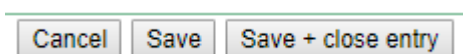
- *Do not record regular data here.*
- *Use this comment field to provide extra information or explanations regarding recorded data.*

- 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 get a consecutive number.

## 7.5 Saving data

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

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



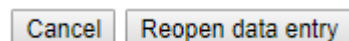
- Click 'Save' if you just want to save data on a form not entirely completed yet.
- Click 'Save + close entry' to finish a form.

Forms closed change their status to 'Date Entry Complete' (DEC) and with it the file color to green. 

**All Forms, that offer the option 'Save and close entry' (not available on more recent 'Casenodes') need to be on status DEC as soon as possible!**

Forms on status DEC are ready for CRA source data verification and validation by DM. The DEC status also makes the forms temporarily un-editable.

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'.



Only if this button is not visible anymore, the form is **finally closed** and can only be edited after a new Query was placed in the section, where data need to be modified.

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

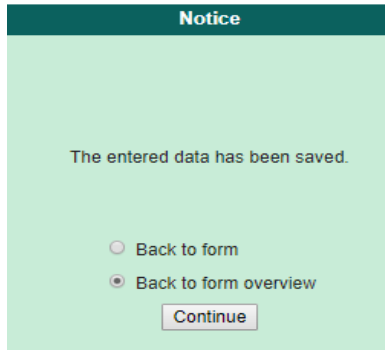
These are information in orange or red color, allocated to data fields, which miss data or have wrong or inconsistent data recorded. When this happens, **immediately provide / correct the data whenever possible and save /close the form again.**

### **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**:

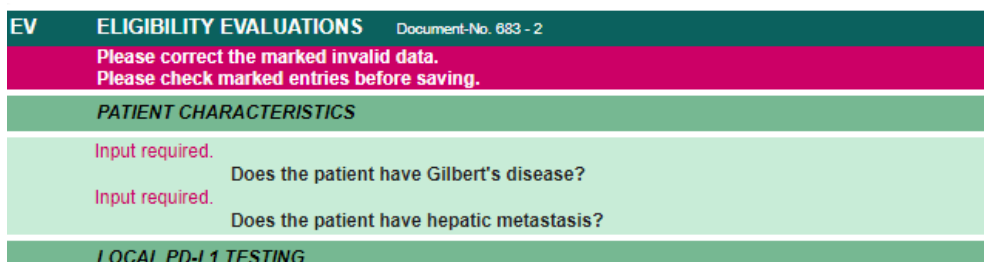
- Press the 'Save' button after recording data. This will trigger the appearance of 'Warnings' on the form. If you cannot resolve them immediately,
- press the 'Save' button a second time. Now you will get a pop up window confirming that the data have been saved and showing navigation options.
- After 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’ (red color) are present**. This happens mainly on Registration and Randomization forms but is not limited to them.

If this happens, a pink 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 will be by using the ‘Cancel’ button. In this case, the data will not be saved.**

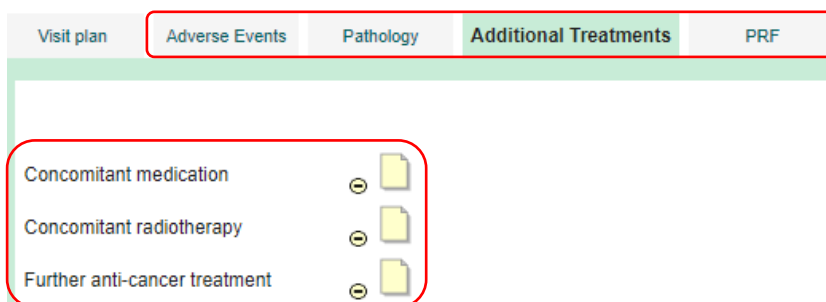
## 8. ‘Casenodes’

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

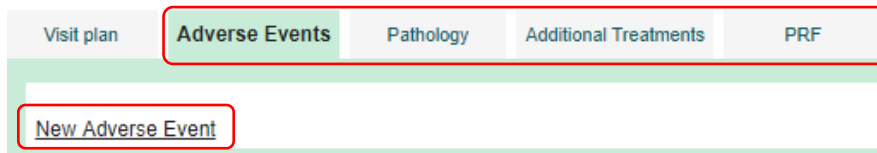
Typical ‘Casenodes’ are Adverse Events and Concomitant Medication. Depending on the trial, there can be others too.

‘Casenodes’ are used to record data, which have to be collected on an ongoing basis and/or can be produced at any not previously defined 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 by creating new events as e.g. for AEs by clicking a respective link.



'Casenodes' already available, contain in recent trials a header question asking for performed examinations, administered medication etc. **These questions have to be answered latest at the end of the time period in which these Casenodes are supposed to be populated e.g. End of treatment, Follow up, etc.**

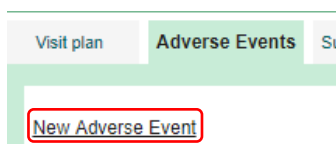
In newer trials, 'Casenodes' intended to be used for ongoing data collection will not need a status change to DEC anymore. They are identifiable by a missing option to save & close the form.

### 8.1 'Casenode' Adverse Events

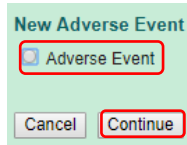
- AEs have to be recorded according to trial protocol chapter 10.
- SAEs have to be recorded according to trial protocol chapter 11.
- For trials with a **paper based SAE reporting process, each SAE reported requires an AE form to be completed in addition** with equivalent data.
- For trials with **eSAE 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**, unless they are SAEs and need to be reported accordingly (see definition in trial protocol chapter 10).
- 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).

#### How to document AEs

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

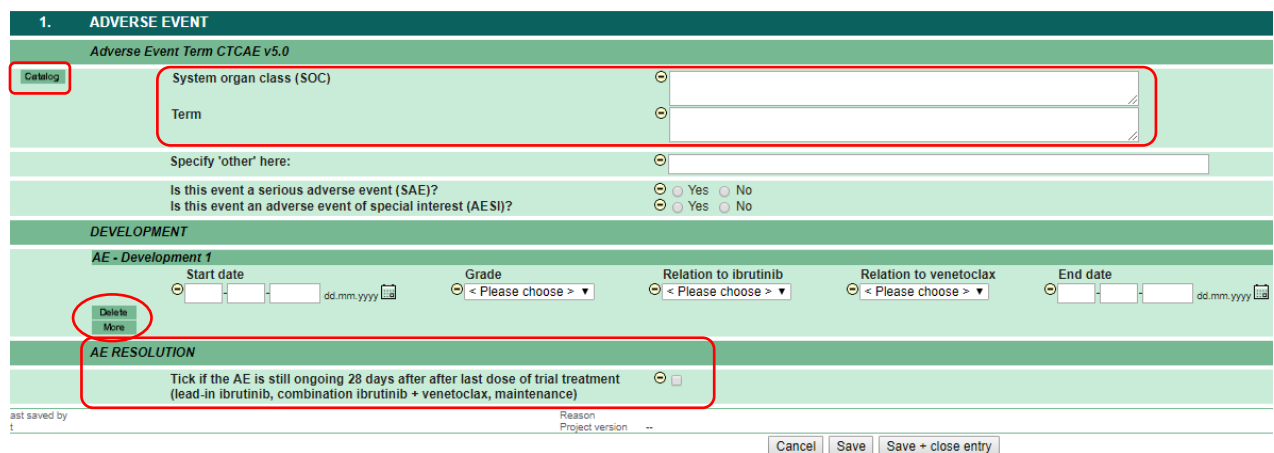


*On a then appearing pop-up window, choose the option Adverse Event and click 'Continue'.*



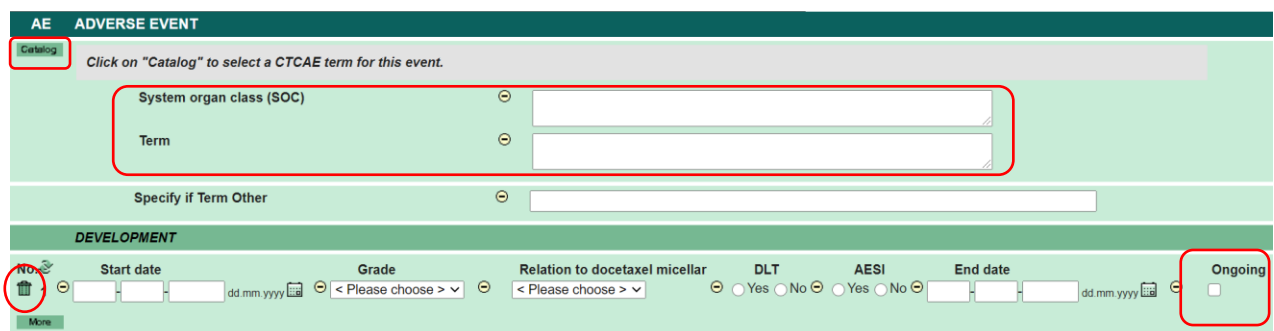
An Adverse Event form similar to the one below opens.

**Older trials:** 'Ongoing' box is available in a separate section below the 'Development' section. The delete option for a development record is indicated by a 'Delete' button.



The screenshot shows the '1. ADVERSE EVENT' form. Key elements are highlighted with red boxes: the 'Catalog' button, the 'System organ class (SOC)' and 'Term' input fields, the 'Delete More' button, and the 'AE RESOLUTION' section with a checkbox. The 'DEVELOPMENT' section includes fields for 'Start date', 'Grade', 'Relation to ibrutinib', 'Relation to venetoclax', and 'End date'. At the bottom, there are 'Cancel', 'Save', and 'Save + close entry' buttons.

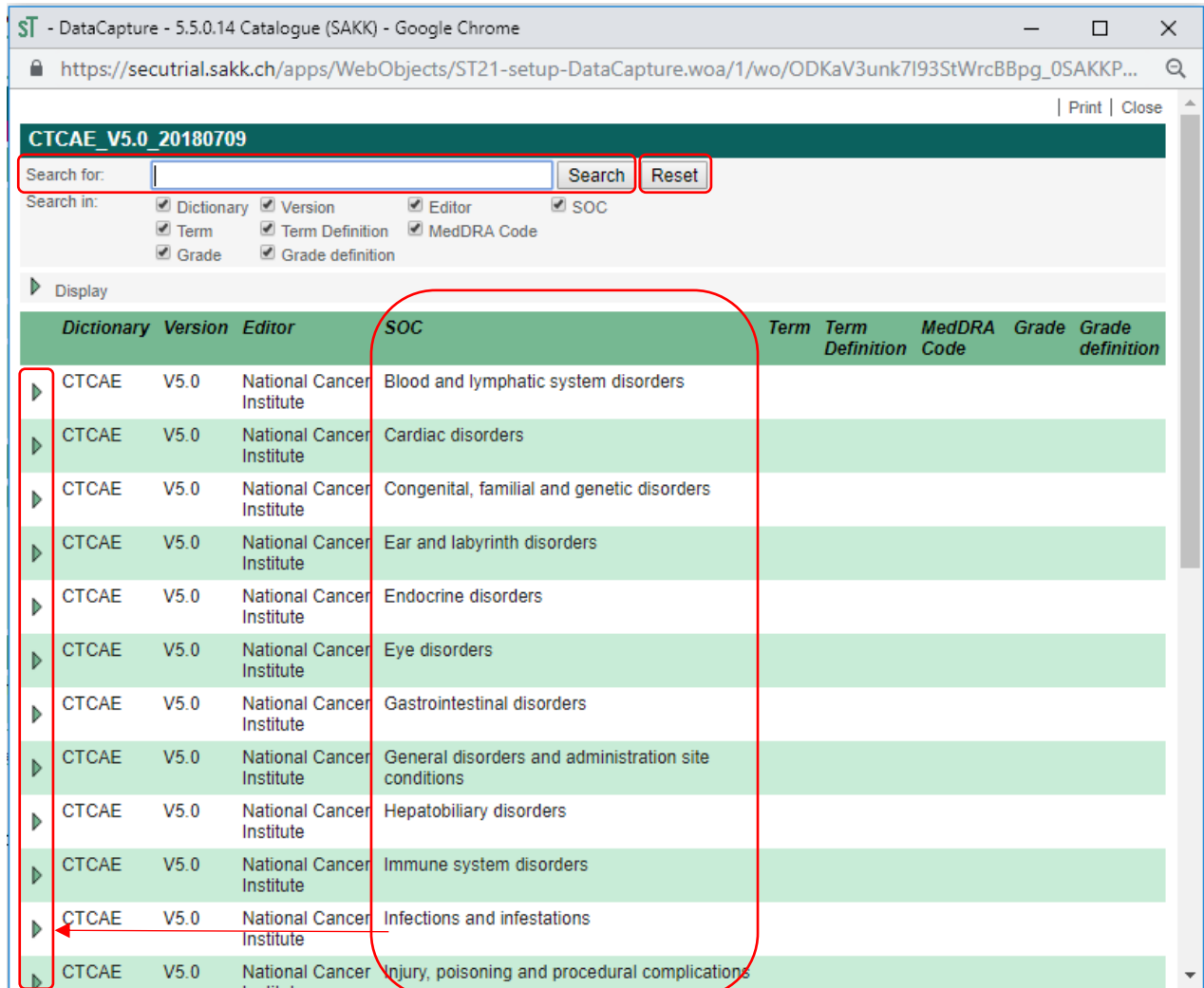
**New trials:** the 'Ongoing' box is available within each 'Development' record. The delete option for a development record is indicated by a trashcan icon.



The screenshot shows the 'AE ADVERSE EVENT' form. Key elements are highlighted with red boxes: the 'Catalog' button, the 'System organ class (SOC)' and 'Term' input fields, the trashcan icon, the 'Ongoing' checkbox, and the 'More' button. The 'DEVELOPMENT' section includes fields for 'Start date', 'Grade', 'Relation to docetaxel micellar', 'DLT', 'AESI', and 'End date'.

Recording SOC and 'Term'.

- 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 in different ways:



CTCAE\_V5.0\_20180709

Search for:  Search Reset

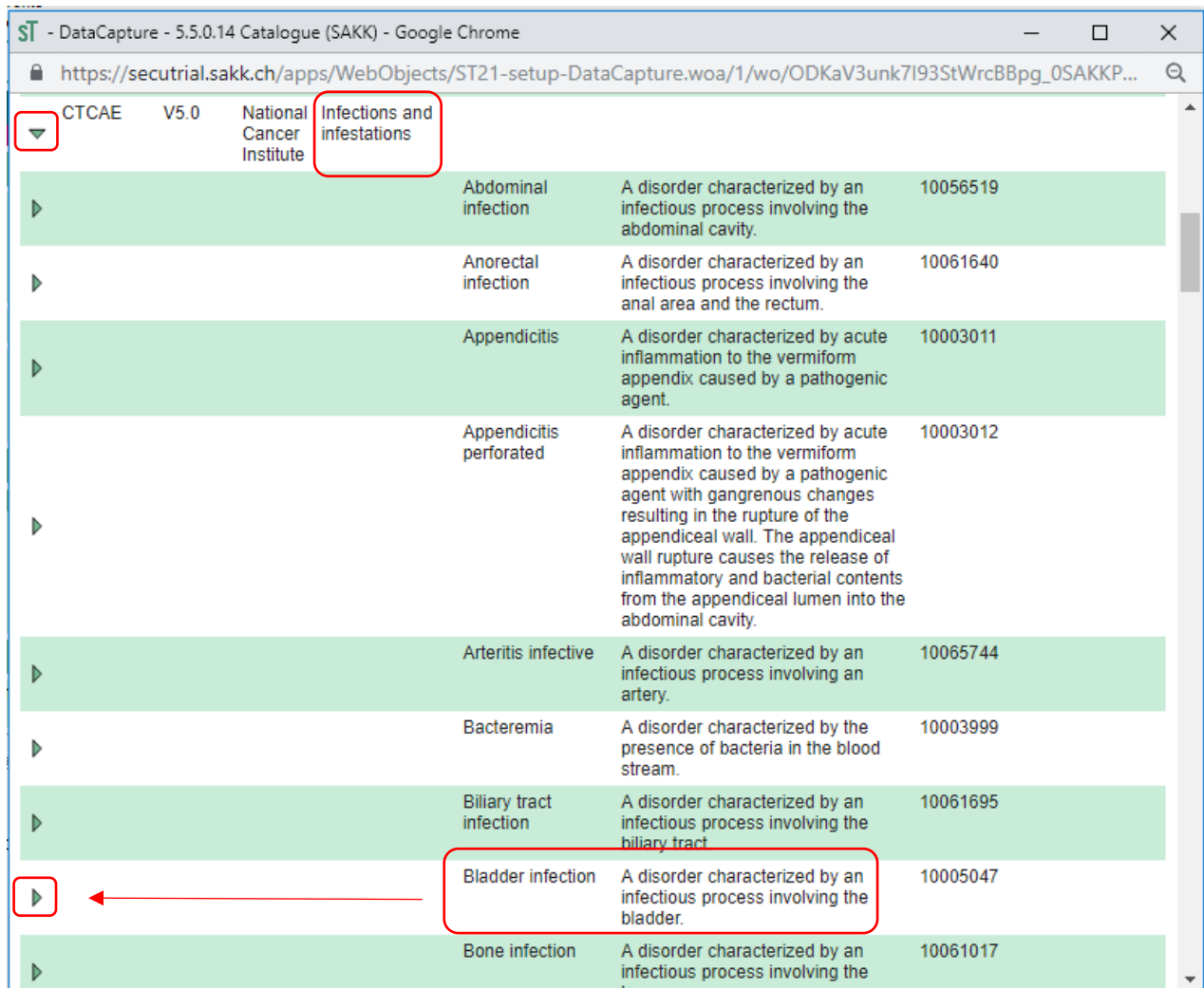
Search in:  Dictionary  Version  Editor  SOC  
 Term  Term Definition  MedDRA Code  
 Grade  Grade definition

Display

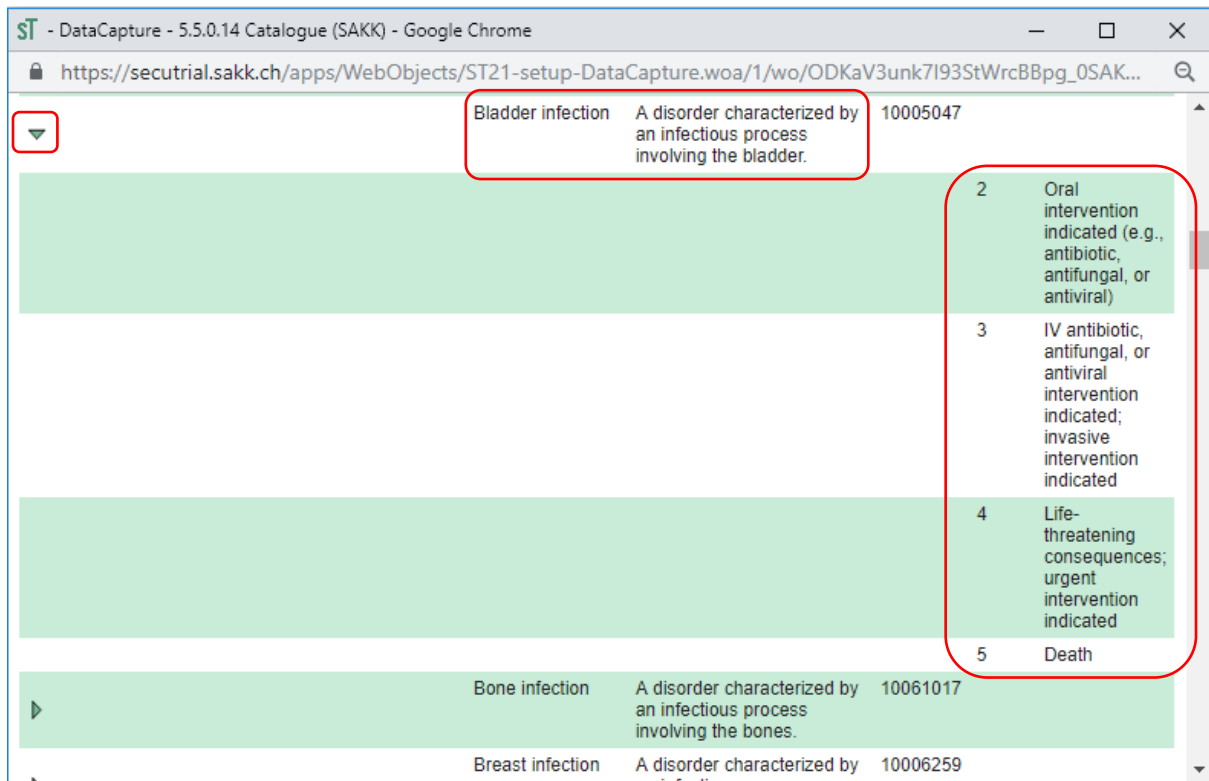
Dictionary	Version	Editor	SOC	Term	Term Definition	MedDRA Code	Grade	Grade definition
▶	CTCAE	V5.0	National Cancer Institute	Blood and lymphatic system disorders				
▶	CTCAE	V5.0	National Cancer Institute	Cardiac disorders				
▶	CTCAE	V5.0	National Cancer Institute	Congenital, familial and genetic disorders				
▶	CTCAE	V5.0	National Cancer Institute	Ear and labyrinth disorders				
▶	CTCAE	V5.0	National Cancer Institute	Endocrine disorders				
▶	CTCAE	V5.0	National Cancer Institute	Eye disorders				
▶	CTCAE	V5.0	National Cancer Institute	Gastrointestinal disorders				
▶	CTCAE	V5.0	National Cancer Institute	General disorders and administration site conditions				
▶	CTCAE	V5.0	National Cancer Institute	Hepatobiliary disorders				
▶	CTCAE	V5.0	National Cancer Institute	Immune system disorders				
▶	CTCAE	V5.0	National Cancer Institute	Infections and infestations				
▶	CTCAE	V5.0	National Cancer Institute	Injury, poisoning and procedural complications				

### 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 this will bring you back to the AE form and only populates the SOC field!
- For example, when searching for the term 'Bladder infection' the SOC 'Infections and infestations' can be chosen:

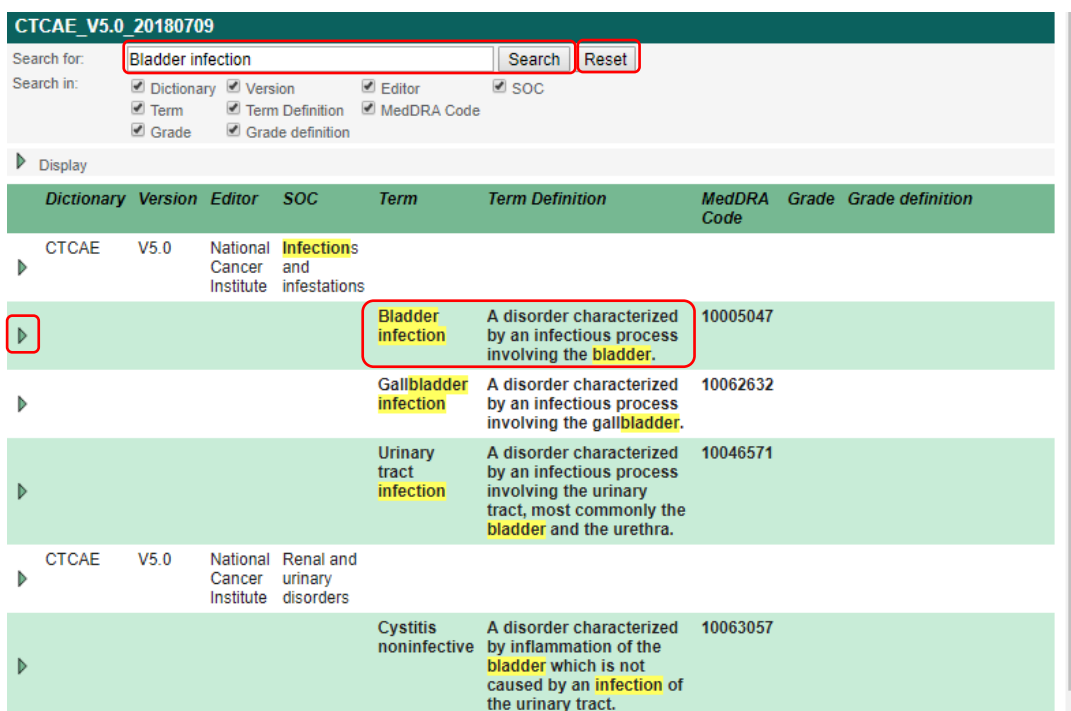


- 'Bladder infection' can be found here. By directly clicking it the AE form will be completed with both SOC and 'Term'.
- To find out about **possible grades** allocated to this 'Term' and the grade definitions, click the associated triangle.
- Here (picture below) we learn that 'Bladder infection' has only 4 possible grades associated in CTCAE. 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 proper grade has to be recorded manually 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)



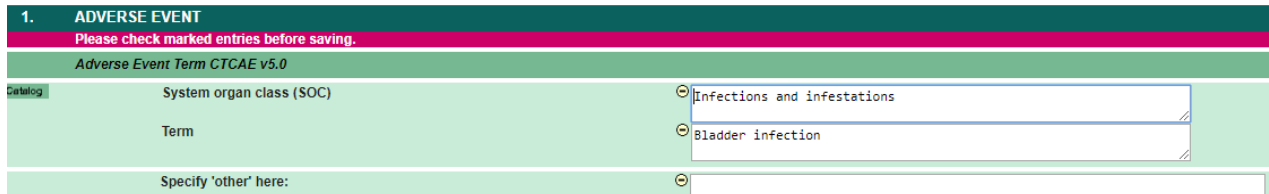
Another option would be to search for the 'Term' directly with help of the **search window** on top of the pop-up window. All SOC and 'Terms' with 'Bladder' respectively 'Infections' will be marked in yellow.

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



Click on 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".

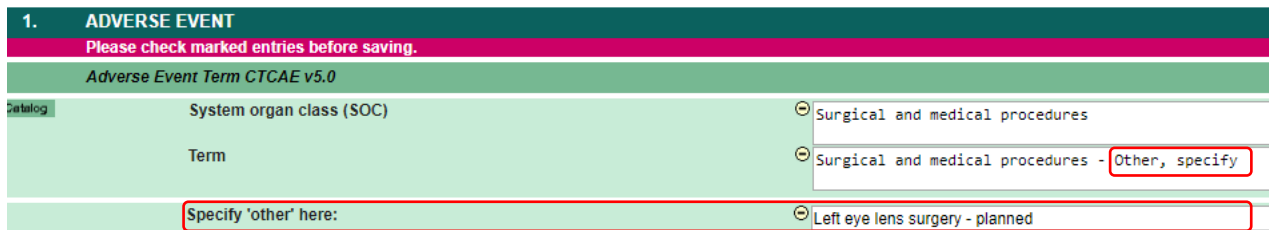


Sometimes the AE term needed is not part of the CTCAE.

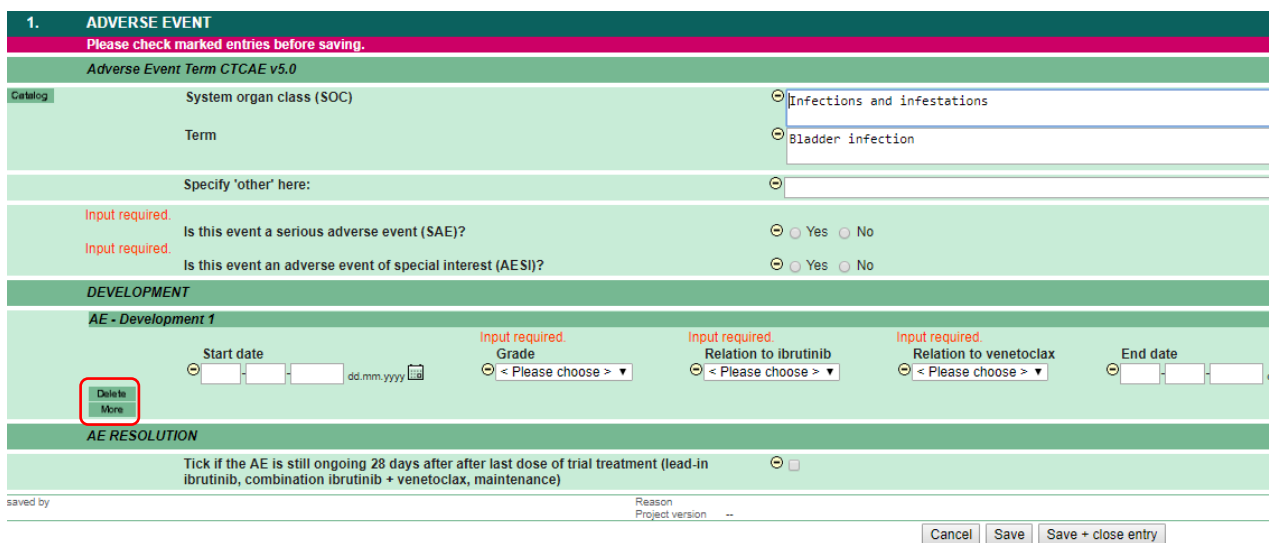
**ONLY for those cases**, each SOC sub menu contains at the very last position the 'Term':

**SOC name – Other, specify.**

When using it, 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.



Using paper based SAE reporting, 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 the **stop date/ongoing** is not clear on an older trial with paper based SAE reports, the form need to be saved although a 'Warning' is available (the Save button has to be used in a 2 step process; 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.

On eSAE trials, you have to provide an 'End date' or an 'Ongoing' tick from the beginning. If the AE was ticked 'Ongoing', recheck at the end of the AE recording period, whether an 'End Date' can be provided instead.

Fatal AE /SAE reports always need the 'Date of death' as 'End date'. AE / SAE which are NOT the cause of death and are ongoing at the time of death, should be kept as 'Ongoing'.

Whenever the AE is changing in grade or stops and starts over later again, this is considered a 'Development' (a new row needs to be set up via the 'More' button). Developments needs to be recorded **within the same AE form!**

The only **exception** from this is (using the paper based SAE process) when an AE is considered as 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 patient needs 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 match.



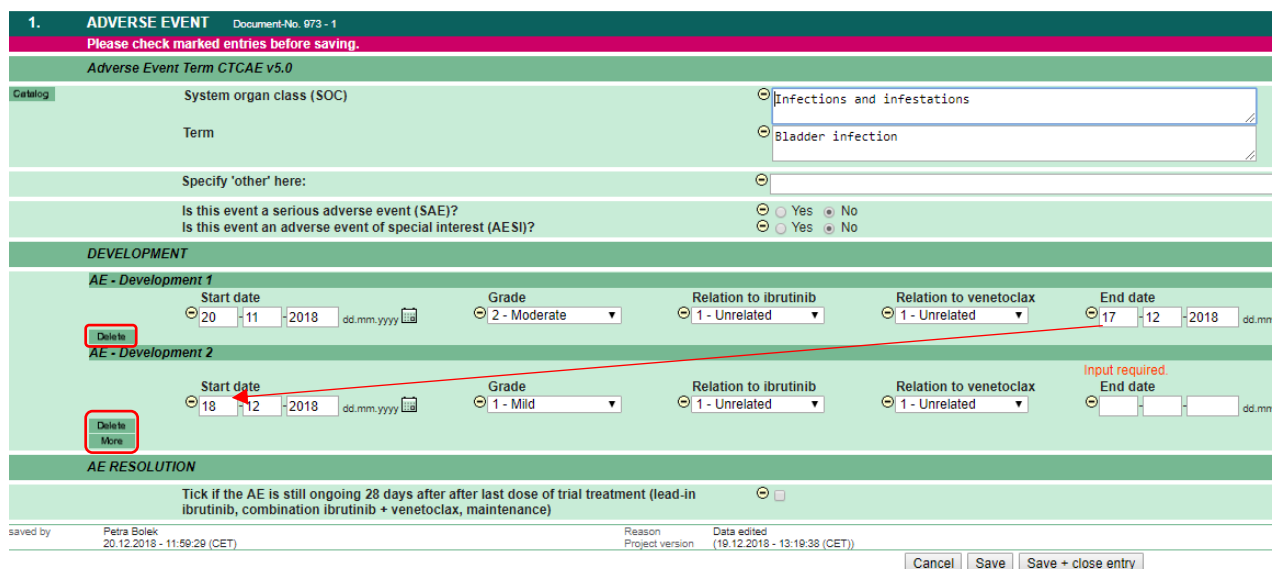
(SOC/Term, Start/Stop/ongoing, Grade)

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

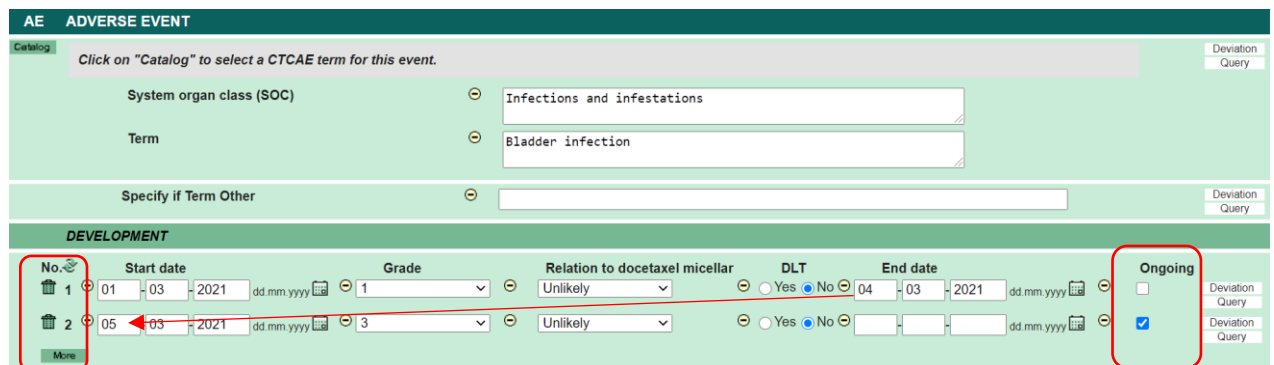
To document a development click the **'More'** button to add a new line.

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

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



In new trials, additionally, a new development can only be started when the previous record has an end date.



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 was 4 weeks ago, on 10.12.2018, and in between there has been an AE but it is not clear when it started and ended. According to the rule above, the start date should be recorded as 11.12.2018 and the end date as 06.01.2019.*

### **How to document SAEs**

For the **paper-based SAE process**, follow the instruction as provided in **protocol section 11**.

For trials with **eSAE process**, the **SAE has to be documented electronically directly in secuTrial by the CRC/PI/SI and needs to be reviewed and signed by the PI/SI**.

The required documentation details are similar to the paper based process, but now **AE & SAE specific data** have to be provided **within one eCRF form**. AE data prior or after the actual SAE still need to be documented separately. Please use the 'Help' buttons on the right-hand side of the eCRF form for more information about each section.

**Be aware that the eSAE is only reported properly, once the SI/PI has signed the document!**

**Only then, Safety Office will receive the notification, and this needs to happen within 24 hours of awareness!**

**A good preparation is important, as it will be no option to save the form with empty fields.**

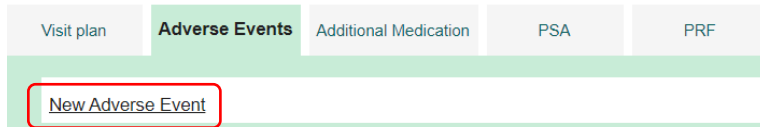
***Therefore, please have all of the following information at hand:***

- 1. Patients characteristics and report information (Sex and 'Year of birth' will be transferred from Registration forms)*
- 2. CTCAE 5.0 Term and grade*
- 3. Causality assessment*
- 4. Development (grade and date)*
- 5. Description of Serious Adverse Event*
- 6. In the investigator's opinion the main event was most likely due to \*\*\**
- 7. Seriousness and Outcome*
- 8. Description of protocol treatment/procedure (this includes all the treatments administered, total daily dose, date of treatment start and date of last administration before SAE onset)*
- 9. Actions taken*
- 10. Treatment and procedures used to treat the SAE \**
- 11. Concomitant treatment and procedures relevant to the SAE \**
- 12. Medical history, Concomitant Diseases and medical conditions relevant to the SAE \**

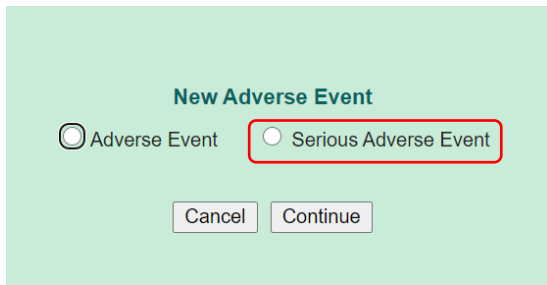
*\*if known at this point. If unknown, this information can be left empty at first and then be updated in the follow up report.*

***\*\*Mandatory if assessed as unrelated to trial treatment***

To create a new SAE, please click on 'New Adverse Event', choose 'Serious Adverse Event' by clicking on the radio button and continue.



The screenshot shows a horizontal navigation bar with five tabs: 'Visit plan', 'Adverse Events', 'Additional Medication', 'PSA', and 'PRF'. The 'Adverse Events' tab is active. Below the tabs, a button labeled 'New Adverse Event' is highlighted with a red rectangular box.



The screenshot shows a dialog box titled 'New Adverse Event'. It contains two radio buttons: 'Adverse Event' and 'Serious Adverse Event'. The 'Serious Adverse Event' radio button is selected and highlighted with a red rectangular box. Below the radio buttons are two buttons: 'Cancel' and 'Continue'.

Please fill in all requested items:

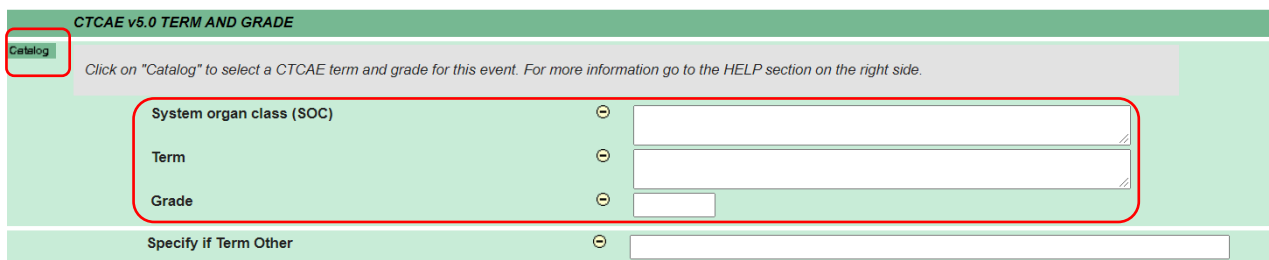
Within the first SAE section, 'Sex' and 'Year of birth' of the patient will be automatically transferred from the EV form.

In section, 'CTCAE 5.0 Term and Grade' document all requested data using the catalogue function. **Do not try to manually record SOC or 'Term'** (further information can be found in section [How to document AEs](#)).

In contrast to the old AE form, also the 'Grade' can be **picked and pasted** into the eCRF **via catalogue**.

Only the 'Specify if Term Other' field needs to be populated **manually** if needed.

The information collected in this section, together with the later to be recorded 'Development' data, cover all data previously collected separately in an AE and SAE form. **Therefore, only one form is needed using an eSAE form and no corresponding AE needs to be created** as long the AE did not have a previous or subsequent development.



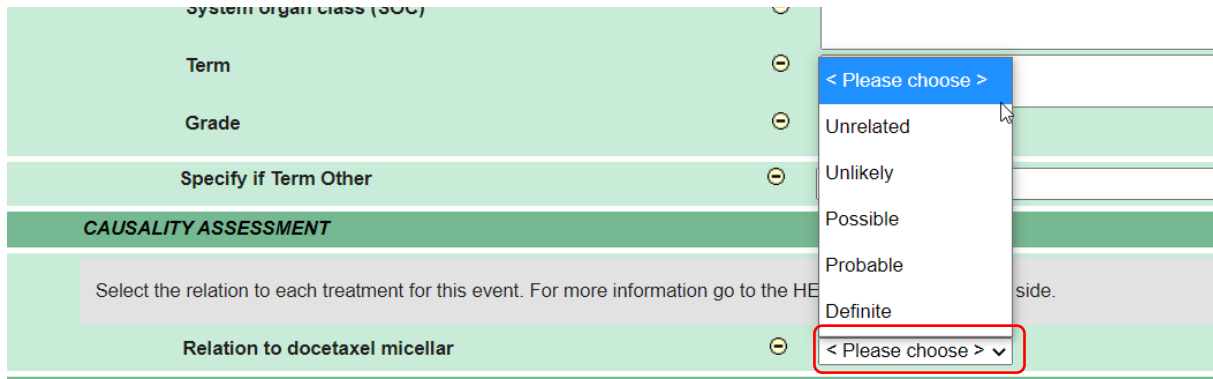
The screenshot shows a form titled 'CTCAE v5.0 TERM AND GRADE'. A button labeled 'Catalog' is highlighted with a red rectangular box. Below the button is a grey instruction box: 'Click on "Catalog" to select a CTCAE term and grade for this event. For more information go to the HELP section on the right side.' Below this are four input fields, each with a dropdown arrow icon: 'System organ class (SOC)', 'Term', 'Grade', and 'Specify if Term Other'. The 'System organ class (SOC)', 'Term', and 'Grade' fields are grouped together and highlighted with a red rectangular box.

For the 'Causality Assessment', please use the dropdown menu and choose the correct relation to each treatment. This should be in accordance with

a) the relation assessment of the respective Development record (to be documented in the next section) and

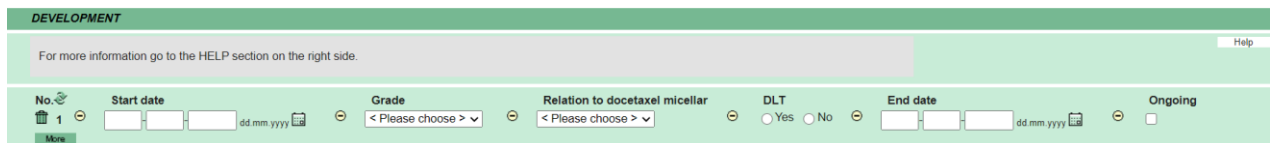
b) with the treatment section further below.

If a **treatment** was **not administered** as indicated in the treatment section, please choose here ‘unrelated’.



The screenshot shows the 'CAUSALITY ASSESSMENT' section of the eSAE form. It includes a dropdown menu for 'Relation to docetaxel micellar' with the following options: '< Please choose >', 'Unrelated', 'Unlikely', 'Possible', 'Probable', and 'Definite'. The 'Unrelated' option is highlighted in blue. Below the dropdown, there is a text field for 'Relation to docetaxel micellar' with a red box around the '< Please choose >' dropdown arrow.

The ‘Development’ needs to be documented as if an AE would be. For the exact documentation, please refer to the chapter [How to document AEs](#). Make sure the data recorded here matches all data provided in other sections within this eSAE form.



The screenshot shows the 'DEVELOPMENT' section of the eSAE form. It includes a table with the following columns: 'No.', 'Start date', 'Grade', 'Relation to docetaxel micellar', 'DLT', 'End date', and 'Ongoing'. The 'Grade' and 'Relation to docetaxel micellar' columns have dropdown menus with '< Please choose >' selected. The 'DLT' column has radio buttons for 'Yes' and 'No'. The 'End date' column has a date picker. The 'Ongoing' column has a checkbox.

There are two free text fields for the description of the SAE and the PI/SI’s opinion (the latter is only necessary if unrelated to trial treatment).

*Please read the grey instruction box for this section carefully.*

**DESCRIPTION OF SERIOUS ADVERSE EVENT**

*Give a detailed description of the SAE, i.e. clinical course of event(s), signs, symptoms, test results, etc.*

No. 
 1

More

**IN THE INVESTIGATOR'S OPINION THE MAIN EVENT WAS MOST LIKELY DUE TO**

*Describe possible causes other than the trial treatment. MANDATORY IF ASSESSED AS UNRELATED TO TRIAL TREATMENT*

No. 
1

*For 'Seriousness and Outcome', every item, with exception of the last three, has to be answered with Yes or No.*

*Depending on the answers given, previously hidden fields on the right site will appear requiring additional information.*

*The 'Date of discharge' can be left empty and updated later in the follow up, if currently unknown.*

*Note that if the outcome is 'fatal', this should also be indicated with 'Grade' 5 above in the 'Development' section as well as in the 'CTCAE v5.0 Term and Grade' section.*

*Always create a separate 'Development' record to document the date of death with 'Grade' 5 and 'Start date' + 'End date' equal to the date of death.*

*If an event was 'Not resolved at death', select 'Ongoing' in the 'Development' section.*



**SERIOUSNESS AND OUTCOME**

Tick all that is applicable. For more information go to the HELP section on the right side.

**Fatal**  Yes  No **Date of death** dd.mm.yyyy

**Specify primary cause of death**

**Was an autopsy performed?**  Yes  No

**Life-threatening**  Yes  No

**Required or prolonged hospitalization (except for elective surgery planned before registration or progression)**  Yes  No

**Date of admission** dd.mm.yyyy **Date of discharge** dd.mm.yyyy

**Resulted in persistent or significant disability**  Yes  No

**Congenital anomaly or birth defect**  Yes  No

**Second/secondary malignancy**  Yes  No

**Other medical important event**  Yes  No

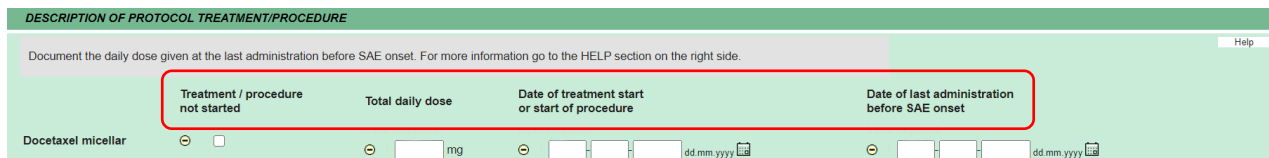
**Resolved without sequelae**

**Resolved with sequelae**  **Date resolved** dd.mm.yyyy **Specify sequelae**

**Not resolved at death**

In the section 'Description of Protocol Treatment/Procedure', please tick the corresponding box underneath 'Not administered' for any trial treatment that was not administered. All the other fields can be left empty under this circumstance.

In case the treatment was administered, fill in the 'Date of treatment start...' as well as the 'Date of last administration before SAE onset' and the 'Total daily dose'.



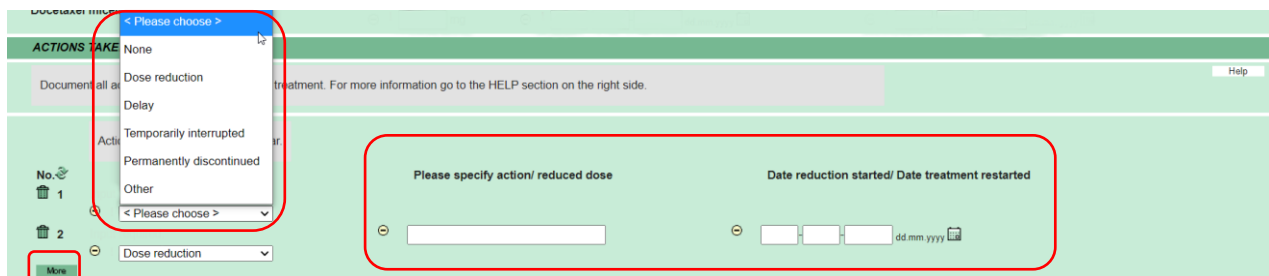
**DESCRIPTION OF PROTOCOL TREATMENT/PROCEDURE**

Document the daily dose given at the last administration before SAE onset. For more information go to the HELP section on the right side.

Treatment / procedure not started	Total daily dose	Date of treatment start or start of procedure	Date of last administration before SAE onset
Docetaxel micellar <input type="checkbox"/>	mg	dd.mm.yyyy	dd.mm.yyyy

Document each 'Action Taken' per treatment. This can be chosen from a dropdown menu. For not administered treatments, please choose the action 'None'. Depending on your selection, please fill in the additionally requested data.

The 'Date reduction started/Date treatment restarted' can be left empty and later updated in the follow up report. The form can be saved despite the 'Input required' Warning, when saved twice. For additional lines, click on the 'More' button.



**ACTIONS TAKEN**

Document all actions taken during treatment. For more information go to the HELP section on the right side.

None  
Dose reduction  
Delay  
Temporarily interrupted  
Permanently discontinued  
Other

**Please specify action/ reduced dose** **Date reduction started/ Date treatment restarted** dd.mm.yyyy

**More**

To provide information about the last three sub forms, the information can be entered if the item is answered with 'Yes'. For additional lines, please click on the 'More' button. If this information is not known at the time the SAE is entered, it can be left empty and updated in the follow-up report.

**TREATMENT AND PROCEDURES USED TO TREAT THE SAE**

Were any treatments and procedures used to treat the SAE?  Yes  No

No.	Generic name of drug or name of procedure	Total daily dose and unit given at most recent administration	Route	Please specify	Start date	End date	Ongoing
1			< Please choose >		dd mm yyyy	dd mm yyyy	<input type="checkbox"/>

**CONCOMITANT TREATMENT AND PROCEDURES RELEVANT TO THE SAE**

Document all relevant drugs or procedures excluding those used to treat the SAE.

Did the patient get any concomitant treatments and procedures which are relevant to the SAE?  Yes  No

No.	Generic name of drug or name of procedure	Total daily dose and unit given at most recent administration	Route	Please specify	Start date	End date	Ongoing
1			< Please choose >		dd mm yyyy	dd mm yyyy	<input type="checkbox"/>

**MEDICAL HISTORY, CONCOMITANT DISEASES AND MEDICAL CONDITIONS RELEVANT TO THE SAE**

Does the patient have any medical history, concomitant disease and medical conditions relevant to the SAE?  Yes  No

No.	Disease group	Specification of disease	Year of onset	Year of onset unknown	Status
1	< Please choose >		yyyy	<input type="checkbox"/>	<input type="radio"/> Not active <input type="radio"/> Active uncontrolled <input type="radio"/> Active controlled

After completing the whole SAE, save the form by clicking on 'Save'.

Validity Not signed

Signature meaning

After saving the form, the CRC will receive an email.

The email needs to be forwarded to the responsible PI/SI for review and for optional change of the data.

The eSAE has to be signed as quickly as possible.

The PI/SI then has to click on 'Sign + save + close entry'.

Validity Not signed

Signature meaning Data edited

The signature needs to be provided by entering the user-ID and password.

After entering the requested items, please click on 'Save + close entry'.

**E-Signature**

By entering your user-ID and password you are confirming that you: **Data entry completed**

User-ID  Password

**Be aware that the eSAE is only reported properly, once the SI/PI has signed the document! Only then Safety Office will receive the notification, and this needs to happen within 24 hours of awareness!**

The SAE and 'SAE upload' will be displayed below the 'Casenode' Adverse Events.



The screenshot shows the 'Adverse Events' tab with three events listed: "Hypertension" (Event-ID 481), "Edema trunk" (Event-ID 482), and "Capillary leak syndrome" (Event-ID 483). Below the list is a summary box containing icons for "Capillary leak syndrome" and "SAE upload".

*If an update needs to be done, please create a 'New follow up' by clicking on the link on the right-hand side of the SAE.*

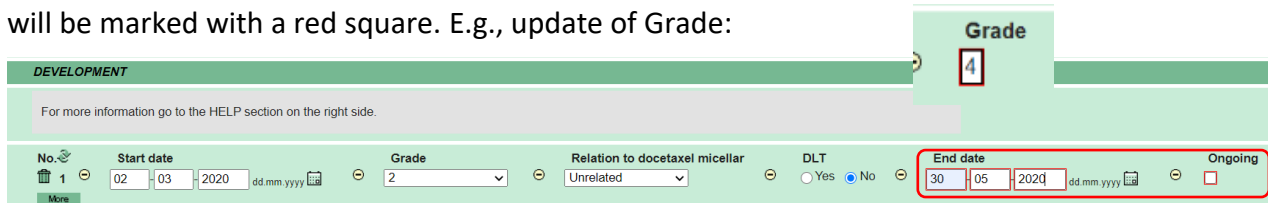
All information provided during first data entry will be transferred to this form. The previous form cannot be changed anymore.

*Document all updates in the follow up form.*



The screenshot shows the 'Adverse Events' tab with the same three events. The summary box below now includes a 'New follow-up' link next to the 'Edema trunk' event icon.

When a correction/change of data is made on the new follow up form, the modified information will be marked with a red square. E.g., update of Grade:



The screenshot shows a data entry form with a 'Grade' dropdown menu. The grade has been updated from 1 to 4, and the number 4 is highlighted with a red square. Other fields include 'Start date' (02/03/2020), 'Relation to docetaxel micellar' (Unrelated), 'DLT' (No), and 'End date' (30/05/2020).

Queries that were not answered before creating the Follow up form will be automatically transferred to the new form. These queries will appear only after saving the Follow up form.

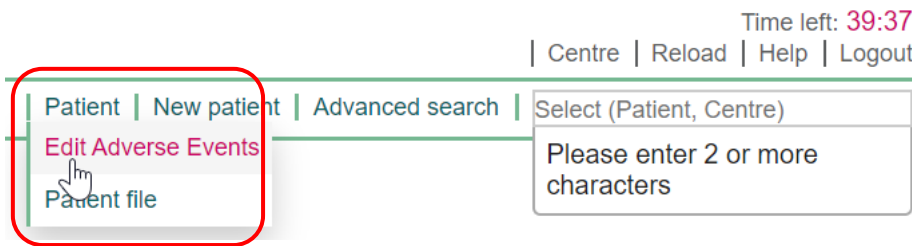
*Please note that in case Safety Office assesses that an eSAE is a 'not reportable/not true SAE', you will be notified. You will then have to document an AE for this event in order not to miss it, if required by the protocol!*



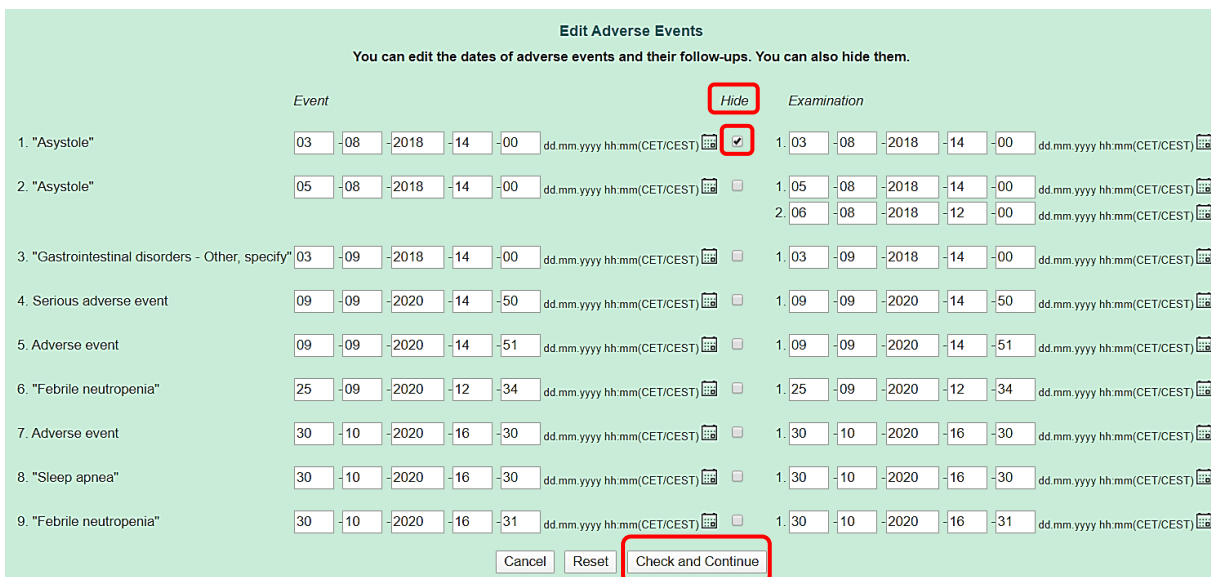
### Hide AE-/SAE forms

It is possible to hide unnecessary AEs or SAEs that were created by mistake and cannot be deleted anymore.

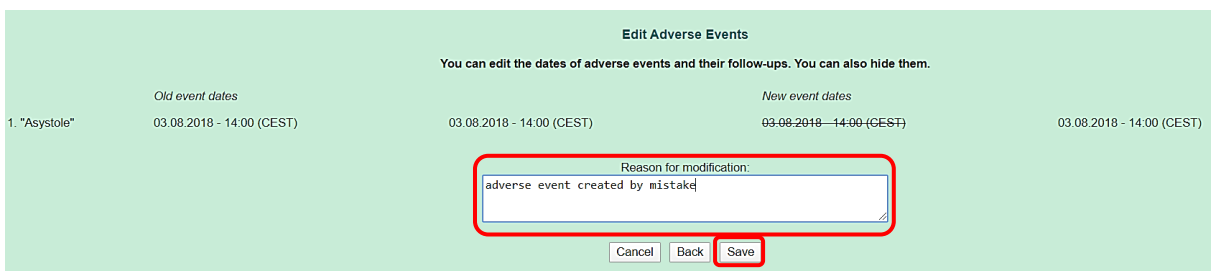
To do so, click on the 'Casenode' Adverse Events, then click on 'Patient' on the upper right-hand side of the screen and choose 'Edit Adverse Event' from the drop-down menu.



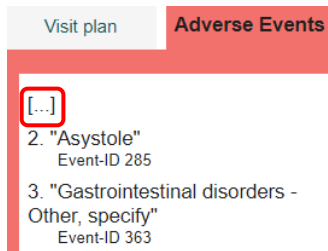
A window opens that allows clicking the 'Hide' box behind the event that has to be hidden:



You will be led to another window where you have to enter a reason for the change and then click on 'Save':



Afterwards, the hidden event will be indicated by **three dots in square brackets**:



By clicking on this placeholder icon, the event will be visible again and can be opened and read. However, editing will not be possible as indicated by the message in the form.

Cancel

This form is in an adverse event which has been hidden. It cannot be edited anymore.

In order to reverse the process and **unhide** the event, repeat the process used for hiding the event: click on 'Edit Adverse Event', remove the tick in the 'Hide' box, enter a reason for the modification and save the change. The event will be visible and editable again.

*Data recorded in forms that are supposed to be hidden, do not need to be deleted previously, as this data will not be part of the statistical analysis or further validation after the forms are hidden. However, already existing **Queries must be answered and closed** before hiding.*

*As for SAEs, only the whole event can be hidden, this is not possible for single follow up forms. In case, such a form was created by mistake, leave the status on 'saved' (not signed) and reopen once you want to use it again.*

*Once an SAE was **signed** and therefore submitted to the Safety Office at SAKK, it **must not be deleted or hidden anymore!***

*In case the event does not qualify as an SAE, Safety Office will mark it as '**not reportable/not true SAE**'.*

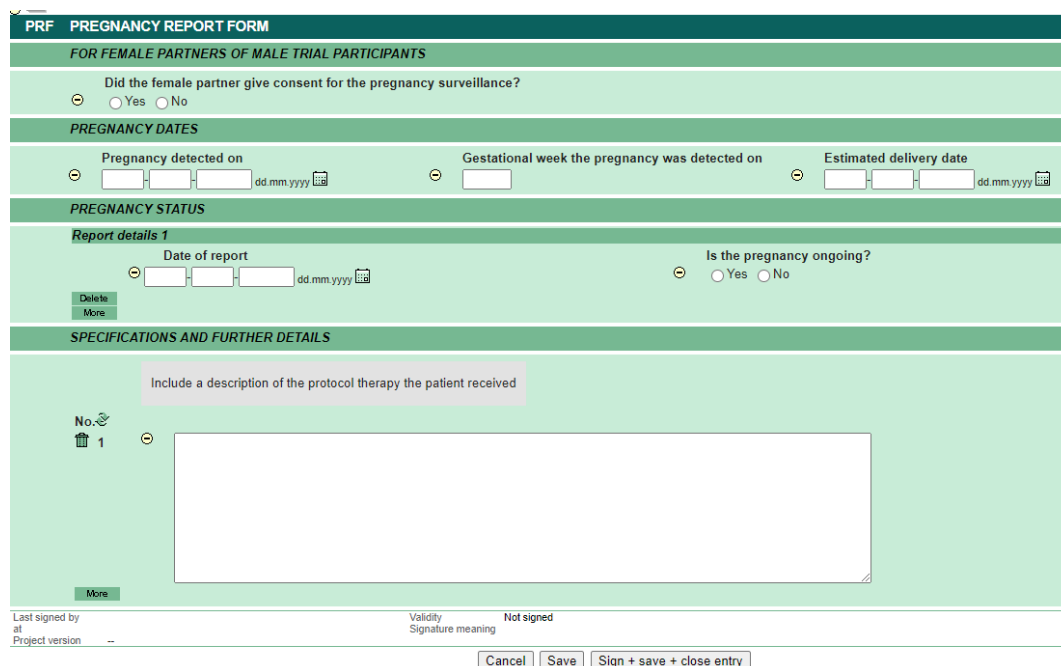
### 8.2 'Casenode' 'Pregnancy Report Form' PRF

For the **paper-based PRF process**, follow the instruction as provided in **protocol section 10**.

For trials with **ePRF process**, the **PRF has to be documented electronically directly in secuTrial by the CRC /PI/SI and needs to be reviewed and signed by the PI/SI equal to the eSAE process**.

**Be aware that the ePRF is only reported properly, once the SI/PI has signed the document!**

**Updates of PRF reports have to be performed within the original form usually by adding records to the 'Pregnancy Status' section via the 'More' button. All updates need to be signed by the PI/SI each time.**



## 9. Query Management


Whenever **data are missing, implausible or inconsistent** Data Management or the responsible 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 based on 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 at the bottom of the page.**

In trials with a high number of patients, Queries might be sent anyway. However, comments are required to explain the situation nonetheless and can be used as reference to answer Queries.

### 9.1 How to find queries

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

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

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

There are two main ways of finding queries:



1. You can directly look for Queries

- Within a patient's 'Form Overview' by typing its UPN into the sT 'Select (Patient, Centre)' field (Do not forget to check 'Casenodes' when doing so) 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

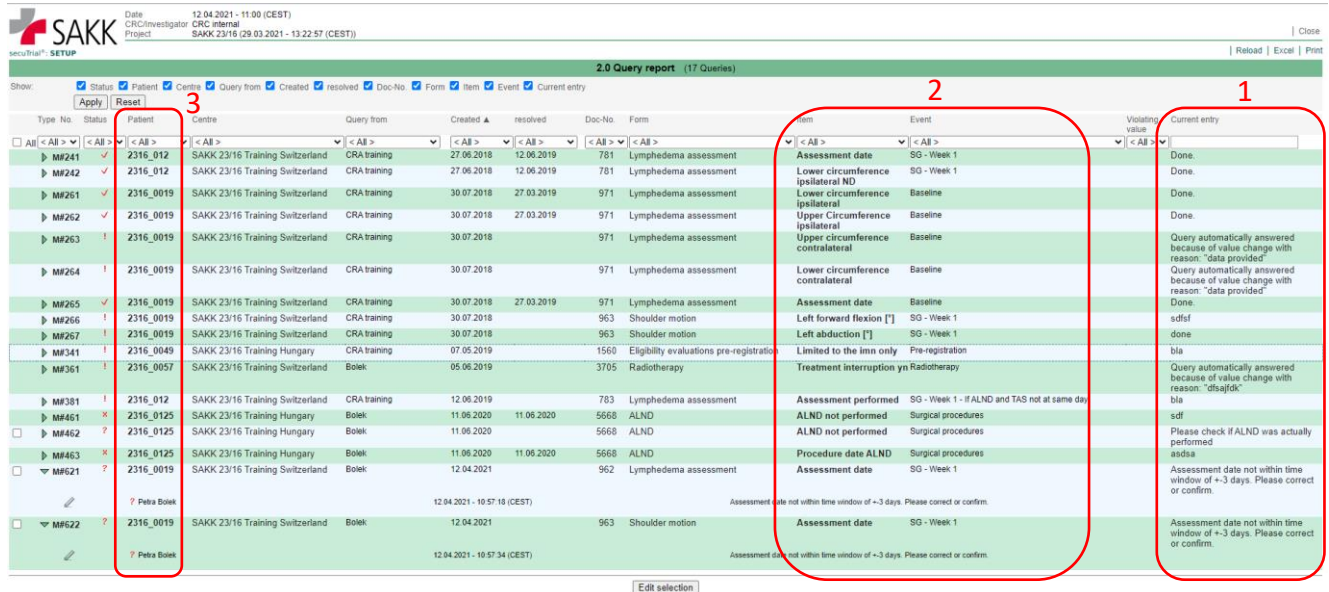
! = Query answered but not resolved by Data Management or CRA yet

✓ = 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 with a detailed Query text on the right hand site (1).

Using the report is quite convenient as it directly opens the form a Query is allocated to by clicking on the respective 'Item' or 'Event?' (2). Clicking the 'Patient' (3) number opens the respective patient's 'Form Overview'.

(See picture on next page)



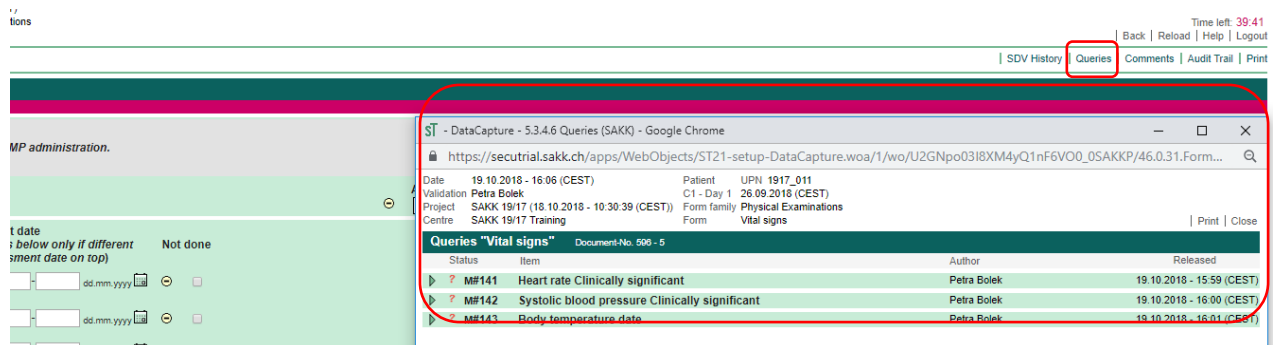
Type No.	Status	Patient	Centre	Query from	Created	resolved	Doc-No	Form	Item	Event	Current entry	Violation value
MF241	✓	2316_012	SAKK 23/16 Training Switzerland	CRA training	27.06.2018	12.06.2019	781	Lymphedema assessment	Assessment date	SG - Week 1	Done.	
MF242	✓	2316_012	SAKK 23/16 Training Switzerland	CRA training	27.06.2018	12.06.2019	781	Lymphedema assessment	Lower circumference ipsilateral ND	SG - Week 1	Done.	
MF261	✓	2316_0019	SAKK 23/16 Training Switzerland	CRA training	30.07.2018	27.03.2019	971	Lymphedema assessment	Lower circumference ipsilateral	Baseline	Done.	
MF262	✓	2316_0019	SAKK 23/16 Training Switzerland	CRA training	30.07.2018	27.03.2019	971	Lymphedema assessment	Upper Circumference ipsilateral	Baseline	Done.	
MF263	!	2316_0019	SAKK 23/16 Training Switzerland	CRA training	30.07.2018		971	Lymphedema assessment	Upper circumference contralateral	Baseline	Query automatically answered because of value change with reason: "data provided"	
MF264	!	2316_0019	SAKK 23/16 Training Switzerland	CRA training	30.07.2018		971	Lymphedema assessment	Lower circumference contralateral	Baseline	Query automatically answered because of value change with reason: "data provided"	
MF265	✓	2316_0019	SAKK 23/16 Training Switzerland	CRA training	30.07.2018	27.03.2019	971	Lymphedema assessment	Assessment date	Baseline	Done.	
MF266	!	2316_0019	SAKK 23/16 Training Switzerland	CRA training	30.07.2018		963	Shoulder motion	Left forward flexion [°]	SG - Week 1	sdfs	
MF267	!	2316_0019	SAKK 23/16 Training Switzerland	CRA training	30.07.2018		963	Shoulder motion	Left abduction [°]	SG - Week 1	done	
MF341	!	2316_0049	SAKK 23/16 Training Hungary	CRA training	07.05.2019		1560	Eligibility evaluations pre-registration	Limited to the Imm only	Pre-registration	bla	
MF361	!	2316_0057	SAKK 23/16 Training Switzerland	Bolek	05.06.2019		3705	Radiotherapy	Treatment interruption yn	Radiotherapy	Query automatically answered because of value change with reason: "data provided"	
MF381	!	2316_012	SAKK 23/16 Training Switzerland	CRA training	12.06.2019		783	Lymphedema assessment	Assessment performed	SG - Week 1 - If ALND and TAS not at same day	bla	
MF461	!	2316_0125	SAKK 23/16 Training Hungary	Bolek	11.06.2020	11.06.2020	5668	ALND	ALND not performed	Surgical procedures	sdf	
MF462	?	2316_0125	SAKK 23/16 Training Hungary	Bolek	11.06.2020		5668	ALND	ALND not performed	Surgical procedures	Please check if ALND was actually performed	
MF463	!	2316_0125	SAKK 23/16 Training Hungary	Bolek	11.06.2020	11.06.2020	5668	ALND	Procedure date ALND	Surgical procedures	asda	
MF621	?	2316_0019	SAKK 23/16 Training Switzerland	Bolek	12.04.2021		962	Lymphedema assessment	Assessment date	SG - Week 1	Assessment date not within time window of +3 days. Please correct or confirm.	
MF622	?	2316_0019	SAKK 23/16 Training Switzerland	Bolek	12.04.2021		963	Shoulder motion	Assessment date	SG - Week 1	Assessment date not within time window of +3 days. Please correct or confirm.	

## 9.2 Query resolution

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

Now there are two main 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 side (provides you only with a listing of Items with queries attached) **or**



MP administration.

Time left: 39:41

Back | Reload | Help | Logout

SDV History | **Queries** | Comments | Audit Trail | Print

ST - DataCapture - 5.3.4.6 Queries (SAKK) - Google Chrome

https://secutrial.sakk.ch/apps/WebObjects/ST21-setup-DataCapture.woa/1/wo/U2GNpo0318XM4yQ1nF6VO0\_05AKKP/46.0.31.Form...

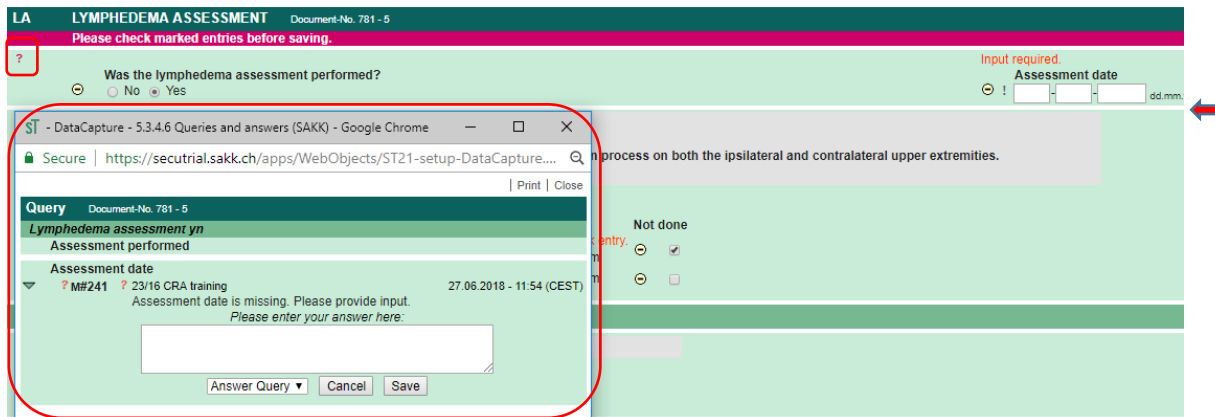
Date: 19.10.2018 - 16:06 (CEST) Patient: UPN 1917\_011  
 Validation: Petra Bolek C1 - Day 1 26.09.2016 (CEST)  
 Project: SAKK 19/17 (18.10.2018 - 10:30:39 (CEST)) Form family: Physical Examinations  
 Centre: SAKK 19/17 Training Form: Vital signs

Print | Close

Status	Item	Author	Released
?	MF141 Heart rate Clinically significant	Petra Bolek	19.10.2018 - 15:59 (CEST)
?	MF142 Systolic blood pressure Clinically significant	Petra Bolek	19.10.2018 - 16:00 (CEST)
?	MF143 Body temperature date	Petra Bolek	19.10.2018 - 16:01 (CEST)

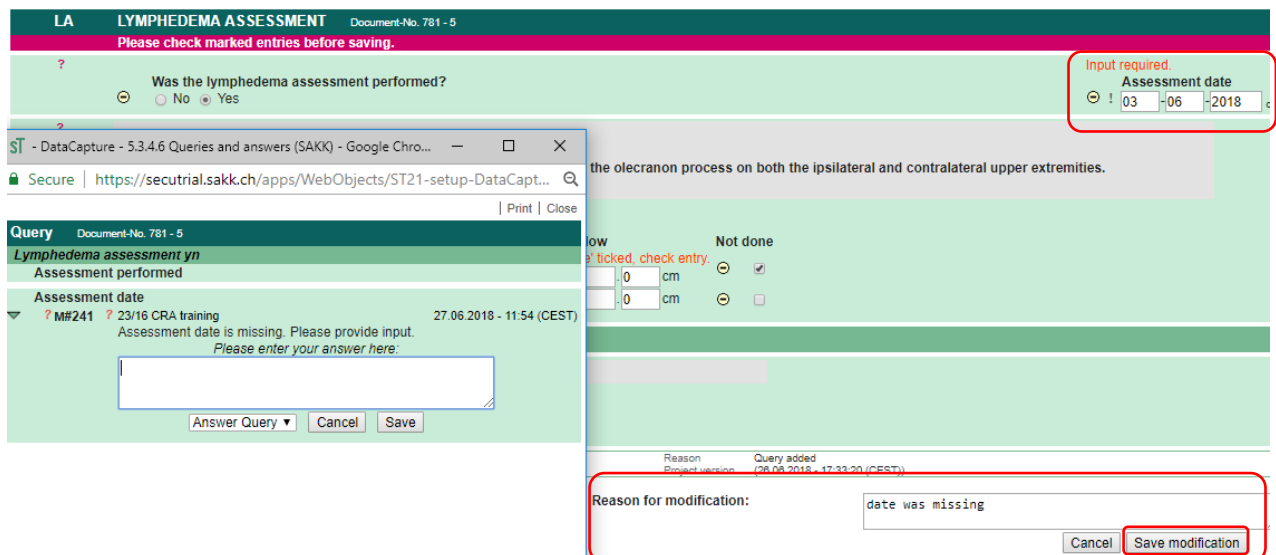
- 2) Look for red question marks (in newer trials Q?) within the form.

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



Whatever you prefer to do, go on by

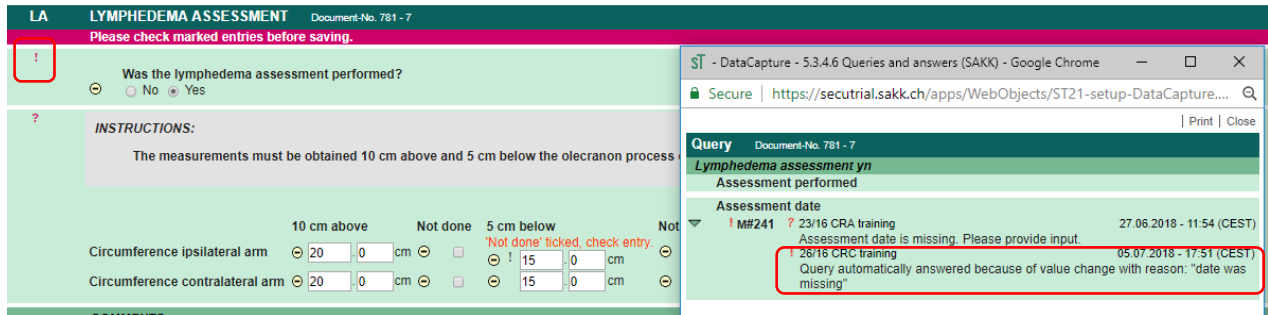
1. Reading the information regarding the Queries to **understand the issues**.
2. Then **fill in the correct data** directly into the respective data fields **on the form!**
3. **Provide the reason for modification at the bottom of the form**. Here you can add additional explanations to Data Management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



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



- 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 (Q).

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.*

- 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 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.
- The section to which a Query is attached, stays modifiable** as long as the answered Query (indicated by and exclamation mark) has not been finally resolved by the Data Manager or the CRA.



open query

answered query

resolved query

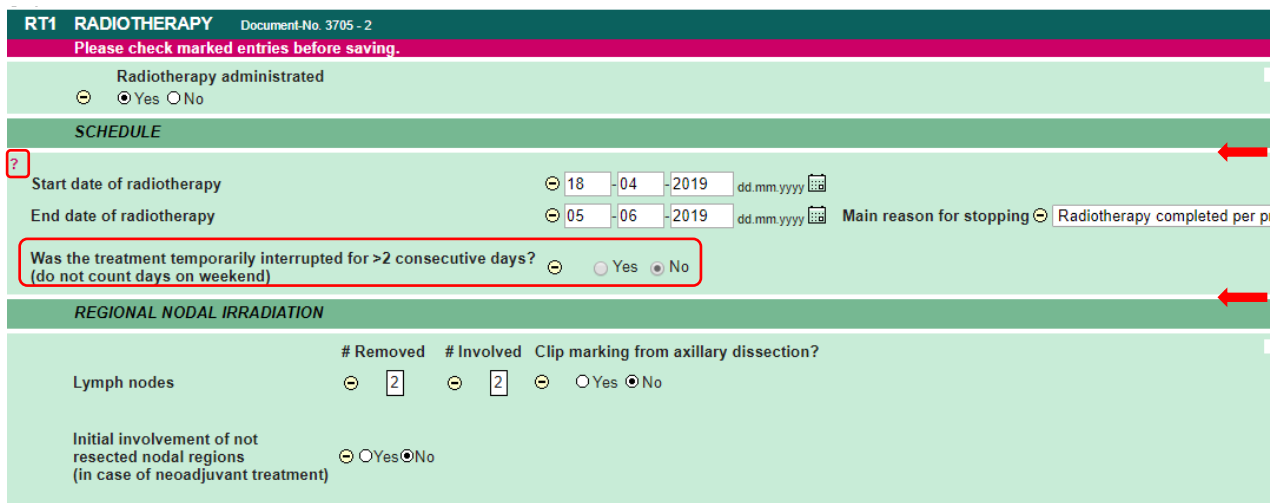
### **Query resolution on formerly hidden and now un-editable sections.**

Query resolution on former hidden sections might **require a two-step approach!**

Often data fields or entire sections are hidden in sT until they are activated by answers given to superordinate items. (See picture next page)

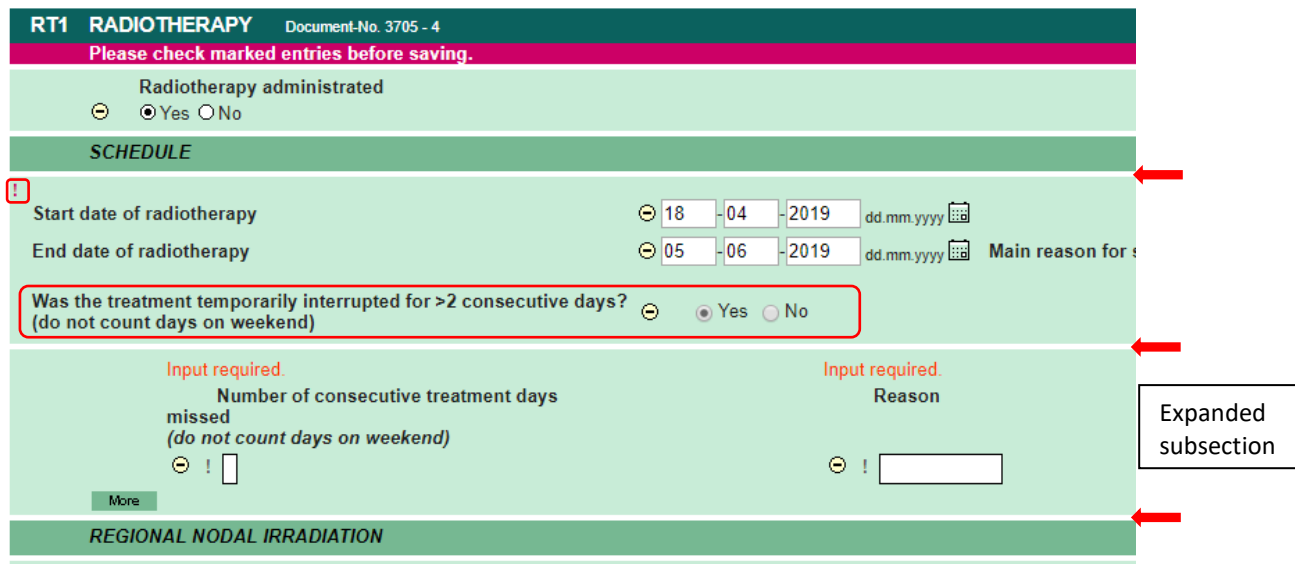
If data fields are **hidden** in a **separate section** (usually separated by white lines) and a **data update due to a Query** on the **superordinate section** triggers the un-hiding of the subsection, this leads to following situation:

**Although the subsection is visible, and despite 'input required' 'Warnings', the section cannot be modified.**



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

As a Query on a form makes the entire form un-modifiable with the exception of the section it is allocated to, the new expanded section cannot be edited.



**To unlock this part of the form, please follow these instructions:**

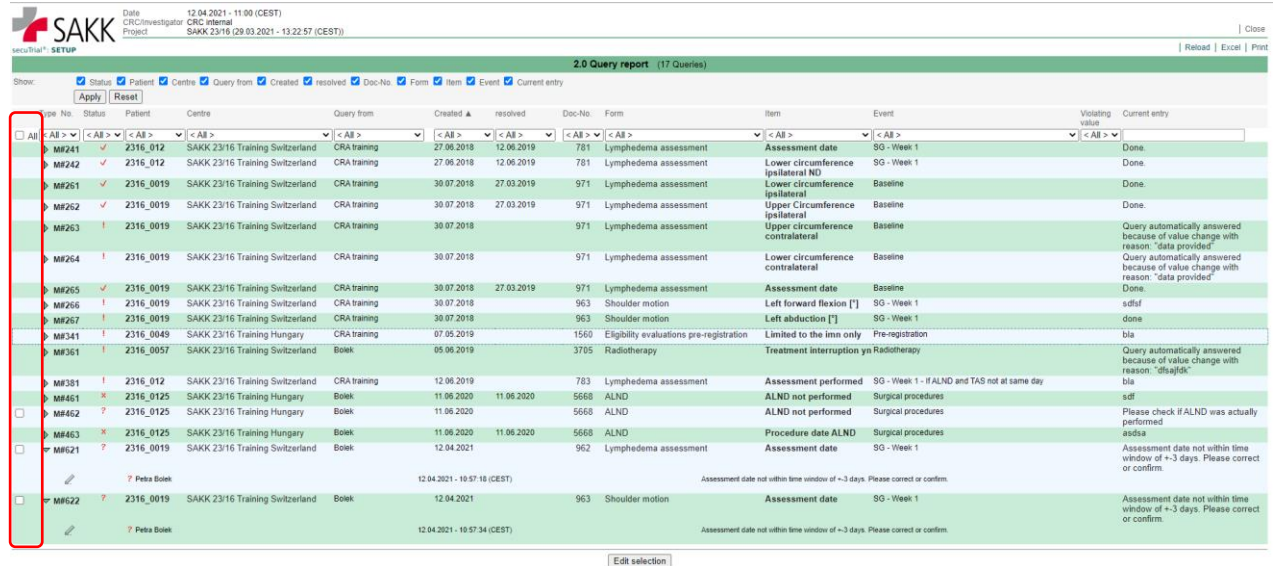
**Step 1:** Save the modification made in the superordinate section to keep the subsection open. Make sure to save the form twice in order to acknowledge the 'Warnings' on the subsection.

**Step 2:** Either wait for the next release of a query batch or proactively contact the Data Manager or the CRA responsible for the study and request a query on the subsection.

Once the query is set, the form can be completed entirely.



### Query resolution using the 2.0 Query report



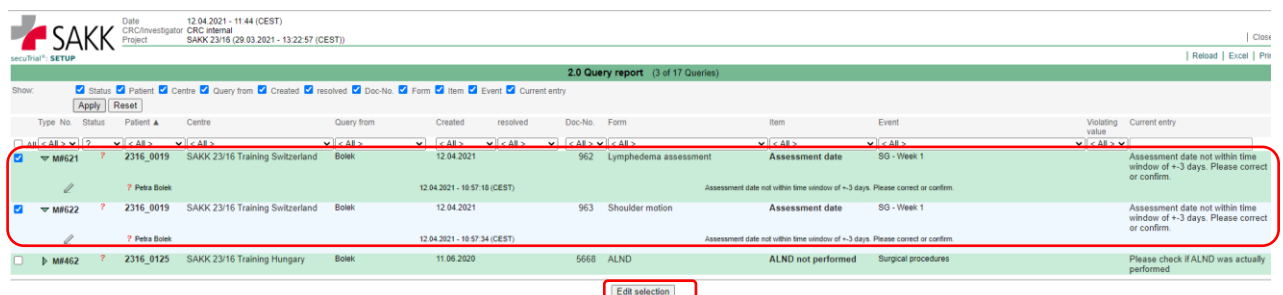
The screenshot shows the '2.0 Query report' interface with 17 queries. On the left side, there are checkboxes for each query, with a red box highlighting the 'open' status queries (MI241, MI242, MI251, MI252, MI253, MI254, MI255, MI256, MI257, MI341, MI351, MI381, MI451, MI452, MI453, MI4621, MI4622). The table columns include Type No., Status, Patient, Centre, Query from, Created, resolved, Doc-No., Form, Item, Event, Violating value, and Current entry.

On the left hand side of the report there are checkboxes available for Queries on status 'open'. They can be used to answer more than one Query at the same time.

**This option has to be used very carefully to avoid answering Queries incorrectly by confusing them! Always back check with the respective form prior answering Queries!**

Additionally, it can only be used for Queries that do not need data changes, but only confirmation/ explanations of data. E.g. 'Out of time window' Queries that need to be confirmed for the same patient and visit but different assessments/ forms.

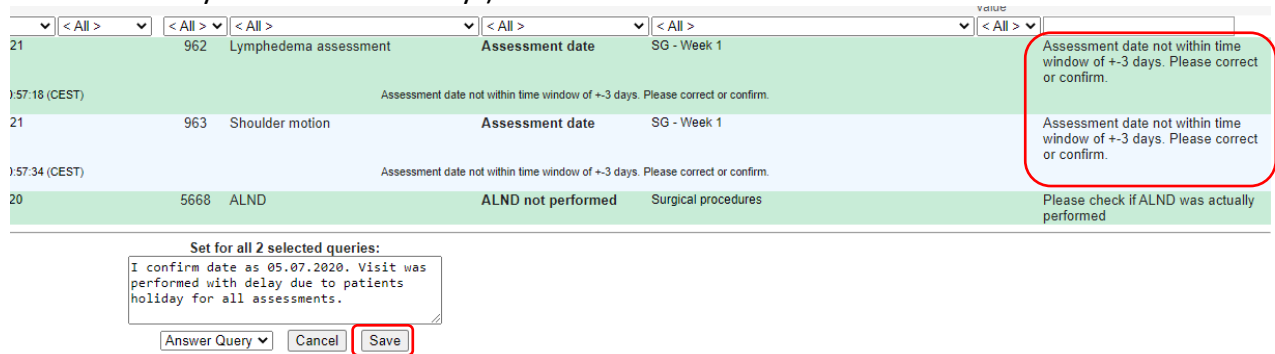
1. Filter for 'open' Queries (?)
2. Sort by patient (click the header 'Patient')
3. If there are many Queries for different patients, it might be helpful to previously filter for one specific patient to avoid any confusion (use the drop down menu below 'Patient' indicated by the '<All>' box to do so.
4. When identifying Queries for the same visit with identical content, and **after you have checked the CRF records against the source data**, you might want to close these Queries all together with the same Query answer.
5. To do so check the boxes on the left hand side for all respective queries



This screenshot shows the same query report as above, but with checkboxes for queries MI4621 and MI4622 checked. A red box highlights these two rows. The 'Assessment date' for both is 12.04.2021, and the 'Violating value' is 'Assessment date not within time window of +3 days. Please correct or confirm.'

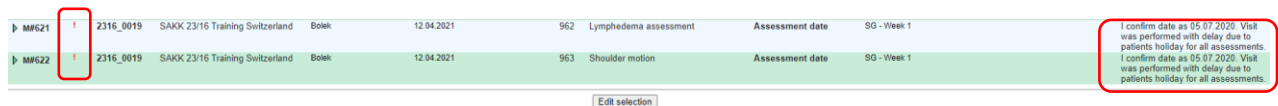
6. Make sure the eCRF form to which they are referring to is closed; otherwise, the following process will not be saved.

- Then click the **'Edit selection'** button below the listing. A window opens requiring the Query answer **valid for all Queries chosen**.
- Add a meaningful text answering the Query (Just 'confirm' or 'done' are not sufficient! Instead describe what you confirm and why!).



The screenshot shows a table with columns for ID, Patient ID, Query Name, Assessment date, and Status. Two rows are highlighted in green, indicating errors: 'Lymphedema assessment' and 'Shoulder motion'. Both have the message 'Assessment date not within time window of +-3 days. Please correct or confirm.' A dialog box is open with the text: 'Set for all 2 selected queries: I confirm date as 05.07.2020. Visit was performed with delay due to patients holiday for all assessments.' The 'Save' button is highlighted.

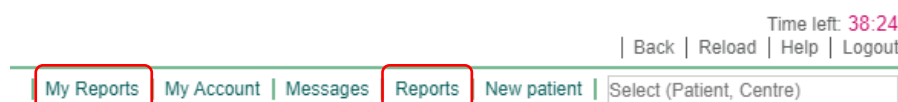
- Save the data.
- Now the 2 marked Queries are answered and have changed their status to 'answered' (!).



The screenshot shows the same table as before, but the two highlighted rows now have a status of 'answered'. The 'Lymphedema assessment' row has a status of 'answered' and a message: 'I confirm date as 05.07.2020. Visit was performed with delay due to patients holiday for all assessments.' The 'Shoulder motion' row also has a status of 'answered' and the same message. The 'Edit selection' button is visible below the table.

## 10. Reports

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



The screenshot shows the navigation bar of the sT 'Welcome page'. It includes a timer 'Time left: 38:24' and links for 'Back', 'Reload', 'Help', and 'Logout'. Below these are buttons for 'My Reports', 'My Account', 'Messages', 'Reports', and 'New patient'. A dropdown menu is open for 'Select (Patient, Centre)'. The 'My Reports' button is highlighted with a red box.

Once you have visited the report page and marked reports as 'My Reports' and have saved this action, the **'My Reports'** button becomes visible and reports can be opened independently from the reports page.



The screenshot shows the 'My Reports' page. On the left, there is a list of reports under the heading 'SAKK 23/16':
 

- 1.0 Patient overview
- 1.1 Important dates
- 1.2 Important dates - Randomized patients only
- 2.0 Query report
- 3.0 Warnings
- 4.0 Missing form status

 On the right, there is a 'My Reports' button with a question mark icon. Below it, there is a list of checkboxes, with the first and last ones checked. A 'Save' button is highlighted with a red box above the checkboxes.

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

> Welcome

### Reports

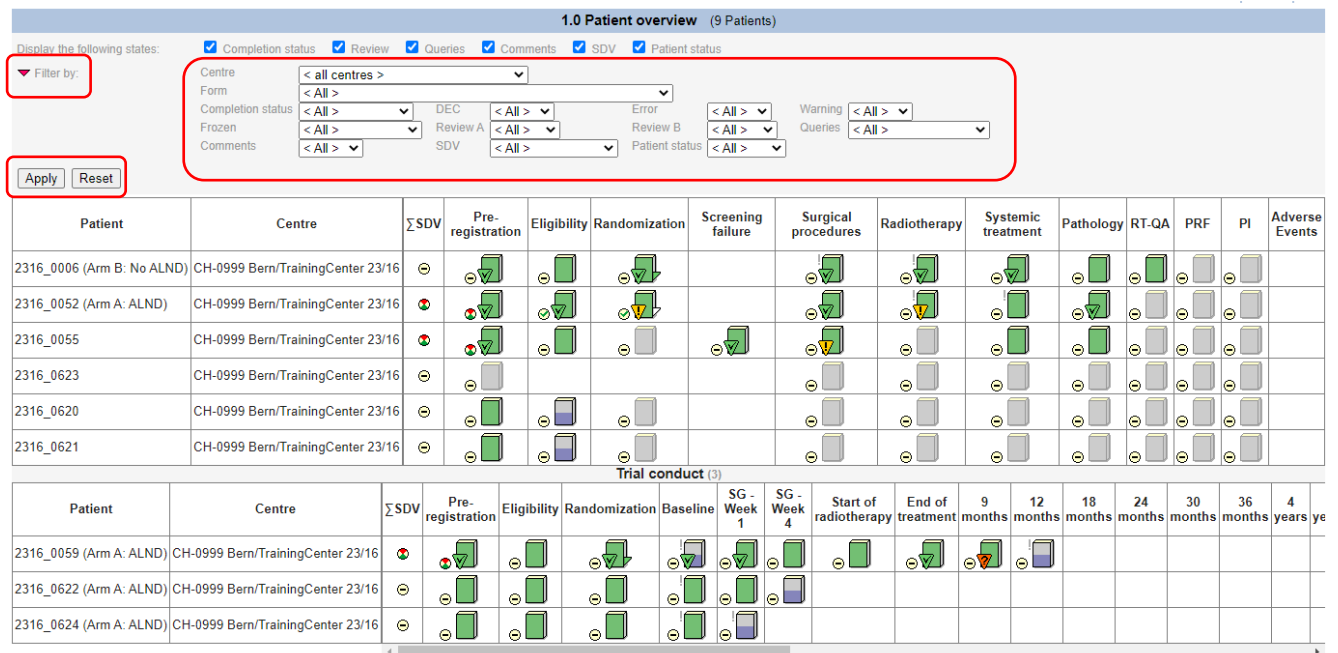
#### SAKK 34/17

- 1.0 Patient overview
- 2.0 Query report
- 4.0 Missing form status

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



**1.0 Patient overview (9 Patients)**

Display the following states:  Completion status  Review  Queries  Comments  SDV  Patient status

Filter by:

Form:

Completion status:  DEC:  Error:  Warning:

Frozen:  Review A:  Review B:  Queries:

Comments:  SDV:  Patient status:

Patient	Centre	ΣSDV	Pre-registration	Eligibility	Randomization	Screening failure	Surgical procedures	Radiotherapy	Systemic treatment	Pathology	RT-QA	PRF	PI	Adverse Events
2316_0006 (Arm B: No ALND)	CH-0999 Bern/TrainingCenter 23/16	⊖	⊖	⊖	⊖		⊖	⊖	⊖	⊖	⊖	⊖	⊖	
2316_0052 (Arm A: ALND)	CH-0999 Bern/TrainingCenter 23/16	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	
2316_0055	CH-0999 Bern/TrainingCenter 23/16	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	
2316_0623	CH-0999 Bern/TrainingCenter 23/16	⊖	⊖	⊖	⊖		⊖	⊖	⊖	⊖	⊖	⊖	⊖	
2316_0620	CH-0999 Bern/TrainingCenter 23/16	⊖	⊖	⊖	⊖		⊖	⊖	⊖	⊖	⊖	⊖	⊖	
2316_0621	CH-0999 Bern/TrainingCenter 23/16	⊖	⊖	⊖	⊖		⊖	⊖	⊖	⊖	⊖	⊖	⊖	

**Trial conduct (3)**

Patient	Centre	ΣSDV	Pre-registration	Eligibility	Randomization	Baseline	SG - Week 1	SG - Week 4	Start of radiotherapy	End of treatment	9 months	12 months	18 months	24 months	30 months	36 months	4 years
2316_0059 (Arm A: ALND)	CH-0999 Bern/TrainingCenter 23/16	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕	⊕					
2316_0622 (Arm A: ALND)	CH-0999 Bern/TrainingCenter 23/16	⊖	⊖	⊖	⊖	⊖	⊖	⊖									
2316_0624 (Arm A: ALND)	CH-0999 Bern/TrainingCenter 23/16	⊖	⊖	⊖	⊖	⊖	⊖	⊖									

- 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 or any respective form.
- 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' button, on a Patient's 'Form Overview'. (See section 5)
- Clicking on the triangle next to 'Filter by' opens the available filter option. After you have chosen, the appropriate ones confirm by pressing the 'Apply' button and only those patients and form will be present fulfilling the criteria. E.g. with filter on 'DEC = without' you get:

**1.0 Patient overview (9 Patients)**

Display the following states:  Completion status  Review  Queries  Comments  SDV  Patient status

Filter by: Centre: < all centres > Form: < All > Completion status: < All > DEC: without Review A: < All > Review B: < All > Error: < All > Warning: < All > Frozen: < All > SDV: < All > Patient status: < All >

Apply Reset

Patient	Centre	ΣSDV	Pre-registration	Eligibility	Randomization	Screening failure	Surgical procedures	Radiotherapy	Systemic treatment	Pathology	RT-QA	PRF	PI	Adverse Events
2316_0006 (Arm B: No ALND)	CH-0999 Bern/TrainingCenter 23/16	⊖												
2316_0052 (Arm A: ALND)	CH-0999 Bern/TrainingCenter 23/16	⊕												
2316_0055	CH-0999 Bern/TrainingCenter 23/16	⊕												
2316_0623	CH-0999 Bern/TrainingCenter 23/16	⊖												
2316_0620	CH-0999 Bern/TrainingCenter 23/16	⊖												
2316_0621	CH-0999 Bern/TrainingCenter 23/16	⊖												

**Trial conduct (3)**

Patient	Centre	ΣSDV	Pre-registration	Eligibility	Randomization	Baseline	SG - Week 1	SG - Week 4	Start of radiotherapy	End of treatment	9 months	12 months	18 months	24 months	30 months	36 months	4 years
2316_0059 (Arm A: ALND)	CH-0999 Bern/TrainingCenter 23/16	⊕															
2316_0622 (Arm A: ALND)	CH-0999 Bern/TrainingCenter 23/16	⊖															
2316_0624 (Arm A: ALND)	CH-0999 Bern/TrainingCenter 23/16	⊖															

This way you can find blank forms, those without status DEC, forms with 'Warnings' or Queries, etc.

## 2.0 Query report

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

secuTrial®: SETUP | Reload | Excel | Print

**2.0 Query report (7 Queries)**

No.	Status	Patient	Centre	Query from	Released	resolved	Form	Item	Event
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

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

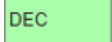
✓ = Query answered and resolved by Data Management

See also section 9. Query Management

### 4.0 Missing form status

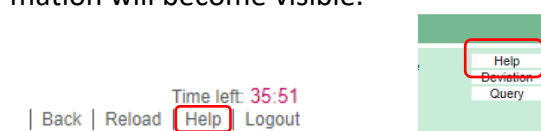
Patient	Pre-registration	Eligibility	Randomization	Baseline	SG - Week 1	SG - Week 4	Start of radiotherapy	End of treatment	Surgical procedures	Radiotherapy	Systemic treatment	Pathology	RT-QA	PRF	PI	Adverse Events
2316_0002	DEC	DEC	DEC	DEC	DEC	DEC			DEC	DEC	Form to complete	Empty form	DEC	Empty form	Empty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

## 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' (GUM)** is stored on the sT Login page, the sT 'Welcome page' as well as on the **SAKK website**.
- SecuTrial as well as single 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

Ver- sion	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
3.0	06.05.2021	All 4.5 6.3 NA 7.5 NA NA NA	Entirely revised version New section - Official 'Data Entry Correction' process for 'Hard Check' controlled data. New section – Hide Visits Update - Laboratory data – recording upper/ lower limits Update - Saving data New section – Hide AEs New section - How to document SAEs Query resolution using the 2.0 Query report	PEB SUR/TLU PEB PEB SUR/TLU SUR/TLU PEB