ObTiMA

eCRF User Manual

V1.4

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1 Introduction to ObTiMA

ObTiMA is multifunctional clinical trial management tool intended for set up and conduct of clinical trials. It is a system for remote data entry, data validation and data management for clinical trials. Furthermore, it offers the possibility for individual design of electronic Case Report Forms (CRF).

1.1 Technical requirements

Besides a connection to the ObTiMA server the following requirements have to be fulfilled:

- Internet Browser:
  - Internet Explorer 9 or higher
  - Firefox 31 or higher
  - Safari 5 or higher
  - Google Chrome 36 or higher
- JavaScript must be activated
- Screen resolution set to 1024 x 768 or greater

1.2 Troubleshooting

For technical assistance and support, please direct inquiries to: info@obtima.org

1.3 Reporting of errors

To report malfunctions of ObTiMA or to send a message/ remark to the ObTiMA developers, please use the “Feedback” button in the very bottom right corner of your browser.

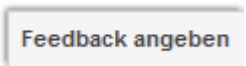


Figure 1: Feedback button

A popup window opens where you can describe your problem and attach files if necessary. Please indicate your name and e-mail address for possible further inquiries.

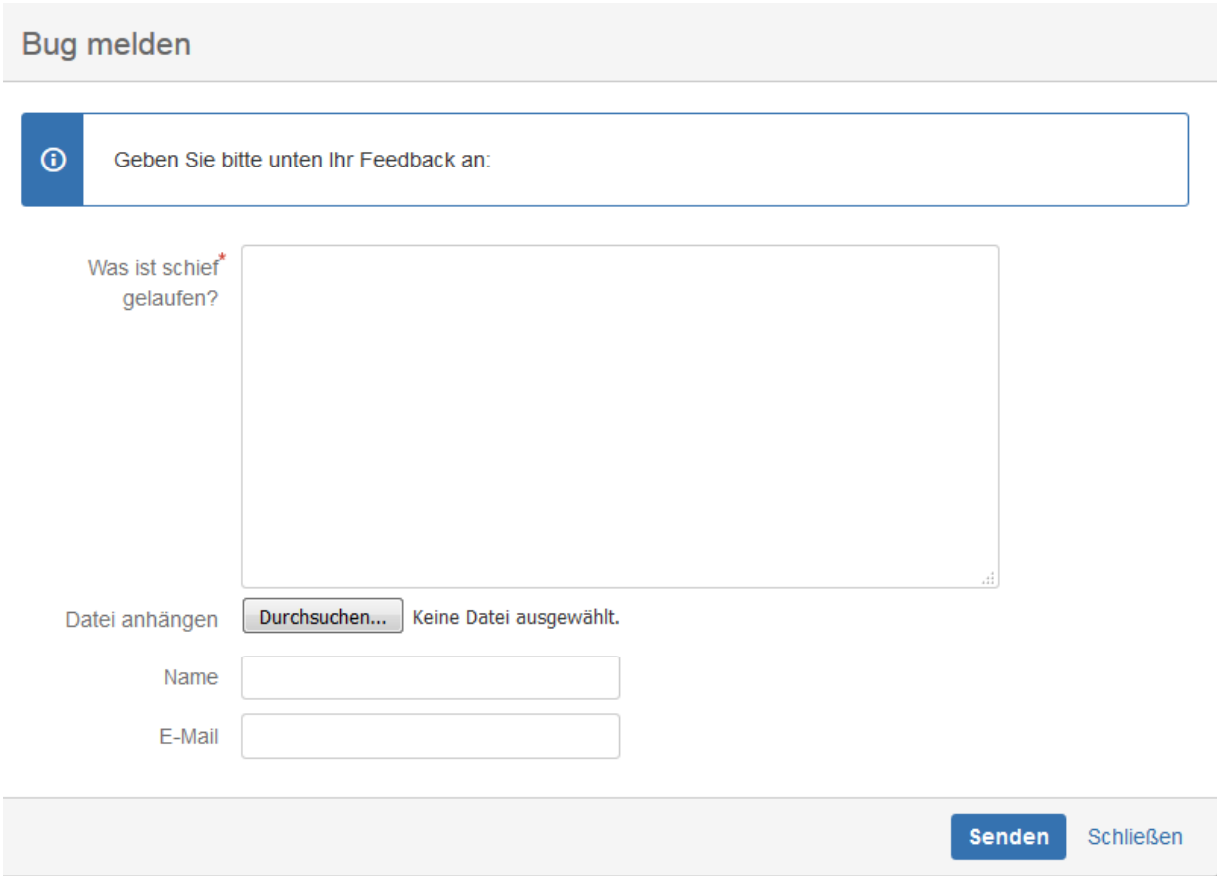


Figure 2: Bug report

After a click at the “Submit” button, the reported phenomena will be investigated by our developers.

2 General Instructions

2.1 Getting started

2.1.1 ObTiMA web address

ObTiMA is located at the following web address:

https://obtima.org/production

2.1.2 Usernames and Passwords

Only authorized study personnel will be assigned a permanent user ID and temporary password. Accounts can be created by your administrator or a respective authorized person with administrator rights. For this purpose, the user's real name, position, organization details as well as e-mail address must be provided. Once the account has been set up, an automatically generated e-mail is sent to the given e-mail address where the user is referred to a link to set a password.

Figure 3: E -mail with login information

Users may be limited to “read only” or may be given permits to enter and update data, provide resolutions to queries and/ or apply electronic signatures. Users are re-

sponsible for maintaining the security of their access to the applications.
In the case of system access issues, requests for new users to be added, or reset of user name or password, please send your request to the technical support/ study coordinator:

2.1.2.1 Edit user details

By left click on the people icon ( ) in the upper right corner of the navigation bar, your personal details will be displayed, that is you can view (trial roles) and edit your user information (user details, login settings).

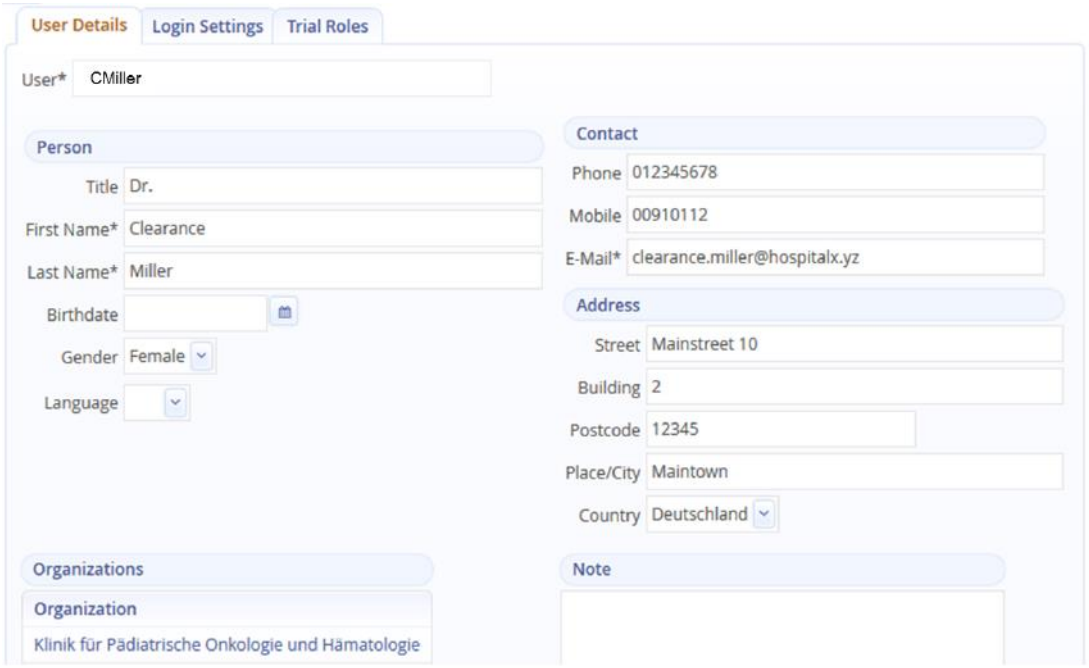


Figure 4: View/ Edit User Details

If you place the mouse pointer over the people icon ( ) in the upper right corner of the navigation bar, your name and user name will be displayed.

Figure 5: User Information

2.1.2.2 Changing password

By left click on the in the upper right corner of the navigation bar, you can change your password (Login Settings).

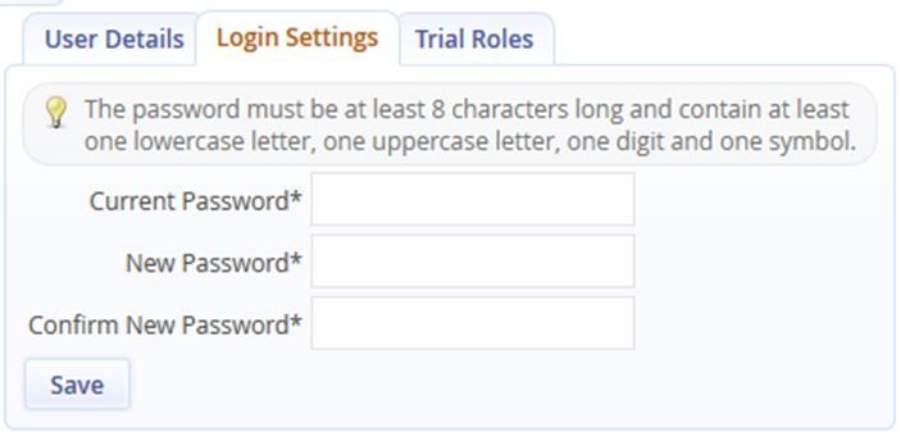


Figure 6: Change password

To change a password, it is necessary to enter your existing password. New passwords require a length of at least 8 characters, consisting of a mix of lowercase and capital letters, numbers and symbols.

2.1.3 Login/ Logout

2.1.3.1 Login

To access ObTiMA, enter your username and password and left click the “Login” button.

Figure 7: Login

The user will be forwarded to the welcome page.

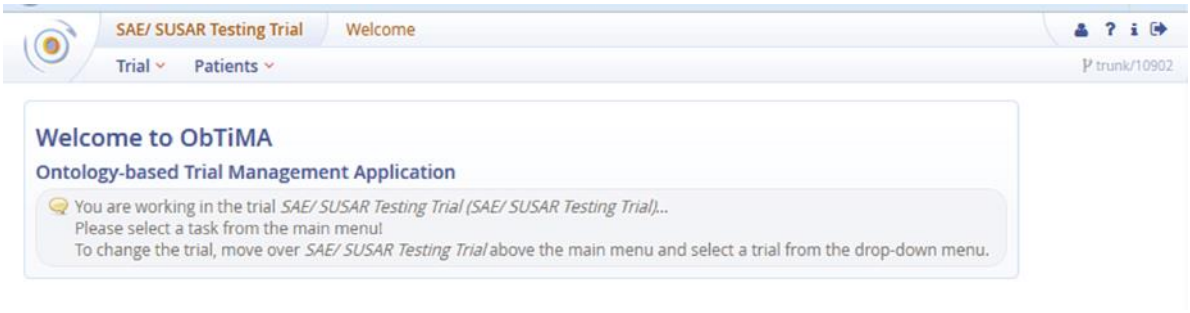


Figure 8: ObTiMA welcome page

NOTE:

- To comply with good clinical practice (GCP) it is very important that users do not share accounts or allow others to access their accounts, even temporarily.

2.1.3.2 Logout

To log out from the site you have to click the 'Log Out' button in the navigation bar at the top right corner of the page.

Figure 9: Logout

NOTE:

- After a period of inactivity (minutes), you will be automatically logged out of the system. 3 minutes before the log out is actually carried out, you will be warned.
- Once you have finished using ObTiMA, it is good practice to log out.

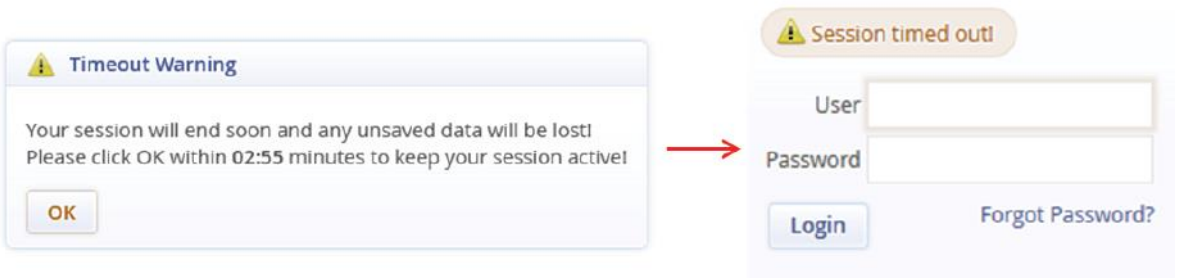


Figure 10: Time Out warning and automatic logout

2.2 Navigation

2.2.1 Icon Key

It is important to become familiar with these icons as they are used regularly throughout ObTiMA.

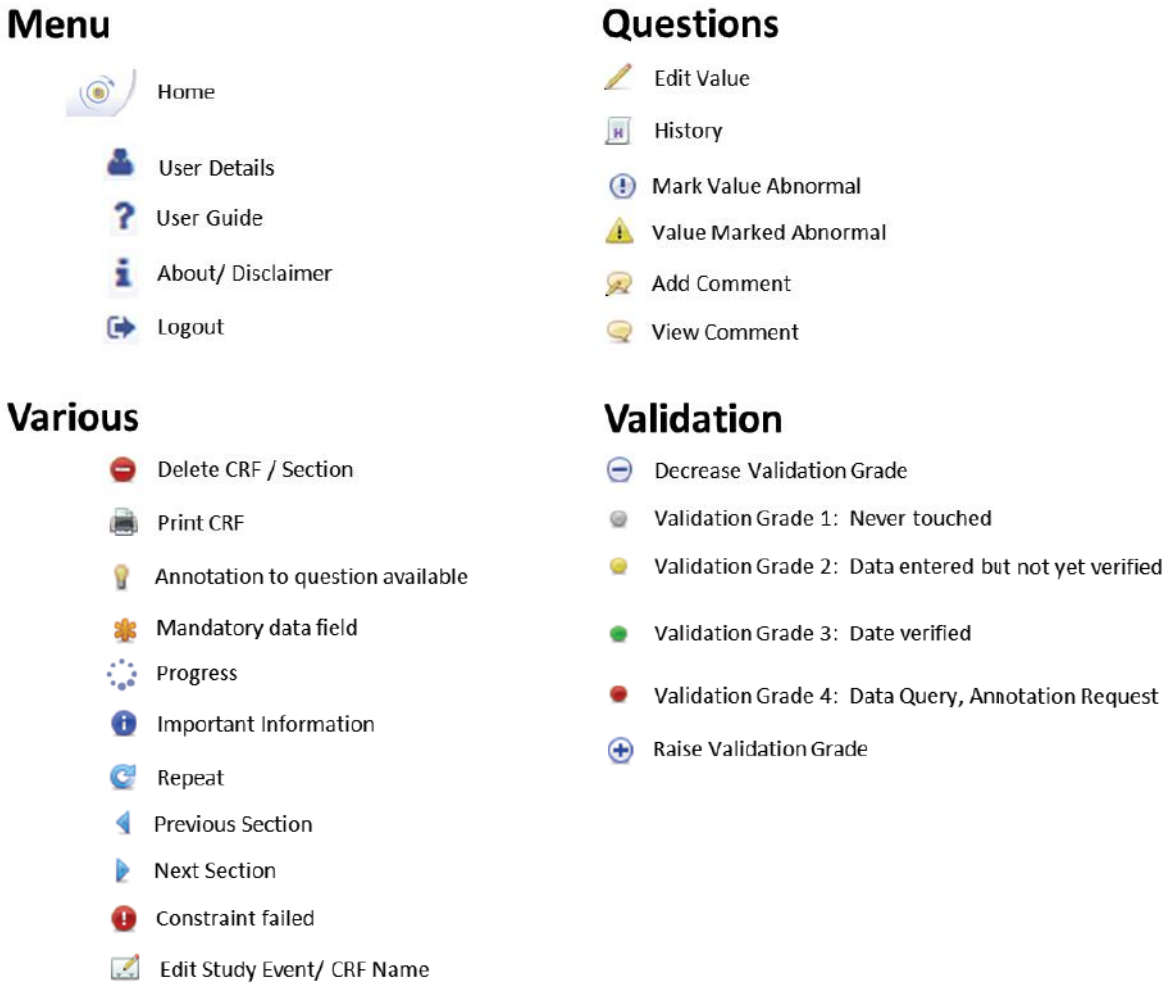


Figure 11: Icon overview

2.2.2 Main navigation bar

After login to ObTiMA, the user will see in the upper right corner the People, User Guide, About/ Disclaimer and Logout icons.

Figure 12: Right side of the navigation bar

: This icon leads to the user's personal details (see 2.1.2.1).

: This icon will navigate the user the ObTiMA eCRF User Manual.

: This icon opens the disclaimer.

: By using this icon, users can manually logout.

On the upper left side of the navigation bar the current trial and right beside, the currently opened menu item are displayed.

The lower left side of the navigation bar contains the "Trial" and "Patients" menu.

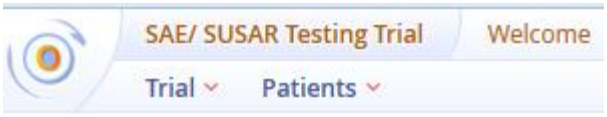


Figure 13: Left side of the navigation bar

2.2.3 Selecting a trial

By opening the ObTiMA eCRF, the study which has been edited most recently will automatically be displayed on the upper left corner of the navigation bar.

To change the current trial, left click on the trial name on the upper left side of the navigation bar. A drop – down list of all trials the respective user is assigned to appears. Chose the trial you wish to work on from the list.

Figure 14: Selecting a trial

2.2.4 Navigation within a selected trial

By clicking on the “Trial” menu and selecting “Manage” a general view of trial specific information is displayed consisting of the Overview -, CRF-, Study Events, Organizations– and Users section.

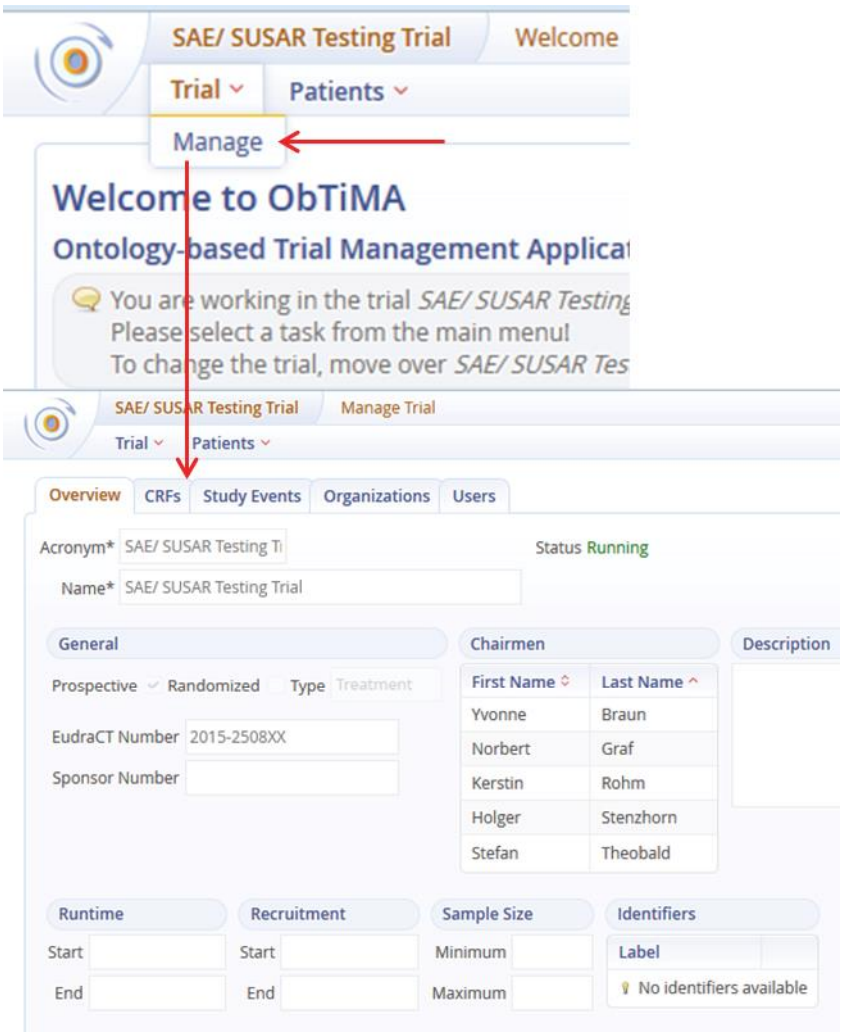


Figure 15: Trials Menu

To open a submenu left click on the respective headers (Overview, CRFs, Study Events, Organizations, Users). To navigate back to the trial overview use the Trial > Manage trials option on the upper left side of the navigation bar (see above).

2.2.4.1 Trial Information

Overview: Basic information on the trial (e.g. study name/ number, description, type, status, duration, recruitment information …)

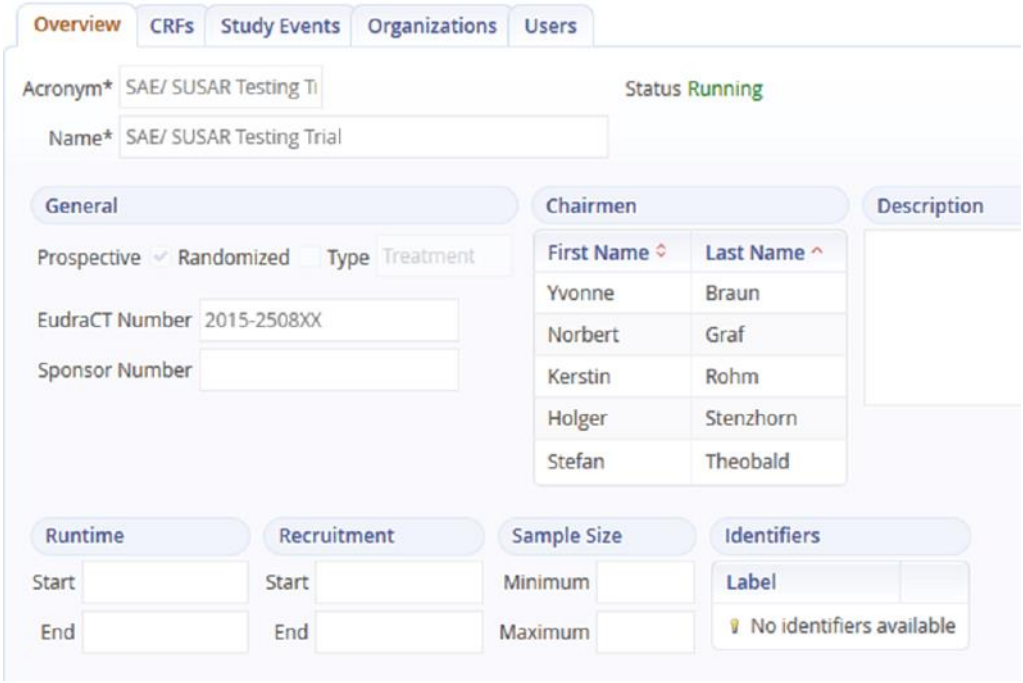
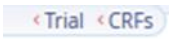


Figure 16: General trial overview

CRFs: List of all available CRFs templates in the trial including CRF details (Name, Version number, date/time of creation, modification and release, CRF status…).

Acronym	Name	Version	Description	Creation Date/Time	Last Modification Date/Time	Release Date/Time	Status
	Adverse Event Form	1.0041	CRF containing AE relevant data as reported by the investigator.	10.09.2015 10:13:29	10.09.2015 10:13:29	10.09.2015 11:27:59	✓
AE	AE Report	1.0052	CRF containing AE relevant data as reported by the investigator.	23.09.2015 10:17:27	23.09.2015 10:17:27	23.09.2015 10:20:15	✓
AE	AE Report	1.0036	CRF containing AE relevant data as reported by the investigator.	11.08.2015 17:43:49	11.08.2015 17:43:49	25.08.2015 11:31:17	✓
AE	AE Report	1.0048	CRF containing AE relevant data as reported by the investigator.	16.09.2015 12:33:39	16.09.2015 12:33:39	16.09.2015 12:34:02	✓
	Clinical Data CRF (Meese)	1.1322	Clinical Data CRF for Human Genetics department	17.07.2014 02:00:00	17.07.2014 02:00:00	Unreleased	✓
	CRF for Chemotherapy	1.0000	CRF for Chemotherapy	17.08.2012 02:00:00	17.08.2012 02:00:00	20.01.2016 11:05:34	✓
	CRF for Pathology	1.0000	CRF for Pathology	17.08.2012 02:00:00	17.08.2012 02:00:00	20.01.2016 11:05:41	✓
	Immunotherapy	1.0163	Leukapheresis Dendritic cell quality Lysate vaccines	01.12.2014 13:21:31	01.12.2014 13:21:31	20.01.2016 11:05:50	✓
F18	IMPORT - Follow-up/Relapse/ Death (F18)	1.0058	Follow-up/ Relapse/ Death (F18)	14.01.2013 01:00:00	14.01.2013 01:00:00	20.01.2016 11:10:36	✓
	Medical History	1.0040		15.01.2013 01:00:00	15.01.2013 01:00:00	20.01.2016 10:52:55	✓

Figure 17: CRF list

To obtain a preview of a specific CRF left click the respective line in the CRF list. To navigate back to the trials menu the user can either click on the 

button on the very left side of the navigation bar or use the Trial > Manage 

option.

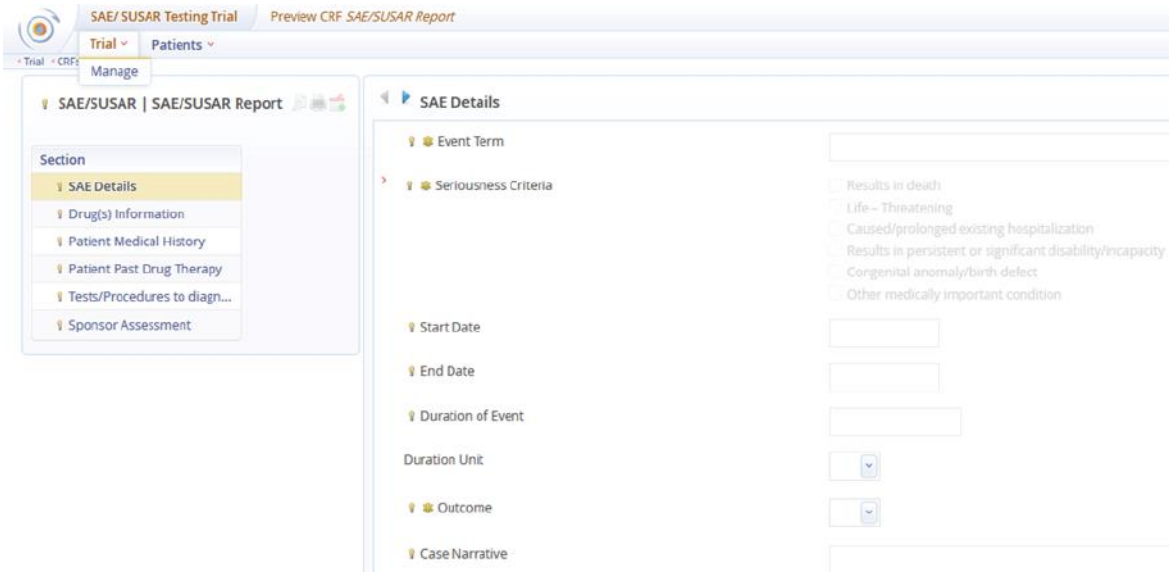


Figure 18: CRF template preview

Study Events: List of all available study events in the trial.

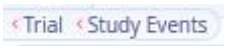
Study events are certain dates predefined in the protocol or other occurrences in the trial where data is captured or created. Each event is assigned an event definition - for example, Screening. A Study Event comprises one or more case report forms (CRFs). An Event can be repeating (occurs more than once) or non-repeating (occurs only once).

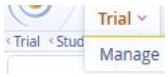
Overview | CRFs | Study Events | Organizations | Users

Acronym	Name	Description	Creation Date/Time	Last Modification Date/Time	Release Date/Time	Status
	Safety Event				Unknown	
	Study Event_4				Unknown	
SE	Safety Event_1				Unknown	
SE	Safety Event_2				Unknown	
	Study Event_3				Unknown	
	Screening	Screening Visit	20.01.2016 10:40:24	20.01.2016 10:40:24	20.01.2016 10:59:35	
	Planned Visit		20.01.2016 10:41:12	20.01.2016 10:41:12	20.01.2016 11:07:04	
	Medical History		20.01.2016 10:41:42	20.01.2016 10:41:42	20.01.2016 11:00:43	
	Follow Up		20.01.2016 10:42:13	26.04.2016 11:25:08	20.01.2016 11:10:54	
	Past and Concomitant Medication		20.01.2016 10:43:07	20.01.2016 10:43:07	20.01.2016 11:02:23	

Figure 19: List of all study events in the trial

To obtain more detailed information on a specific study event (e.g. number and type of assigned CRFs) left click the respective line in the Study Events list. To navigate

back to the trials menu the user can either click on the 

button on the very left side of the navigation bar or use the Trial > Manage 

option.

Figure 20: Detailed information on Study Event

Organizations: List of all participating study sites in the trial.

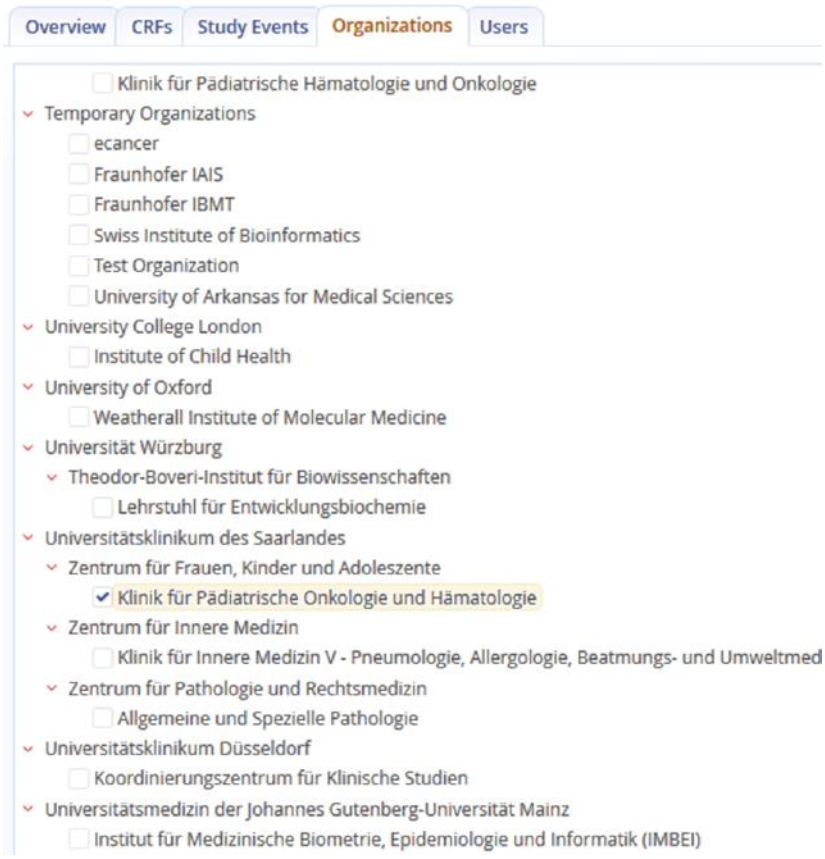


Figure 21: List of all participating sites

Users: List of all users of the local site staff

2.2.5 Navigation within Patients Menu

By clicking on the “Patients” menu and selecting “Manage” a list of all patients enrolled in this study at the location the current user is assigned to will be displayed.

Figure 22: Manage Patients

To sort the list by the different items (pseudonym, first/ last name, birthdate) left click on the particular column name, one click is used for ascending and the other for descending sorting.

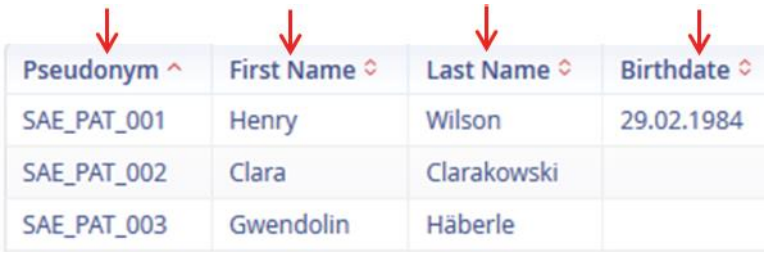


Figure 23: Sorting of patient list

Study specific patient records can be accessed by left clicking the respective line in the list.

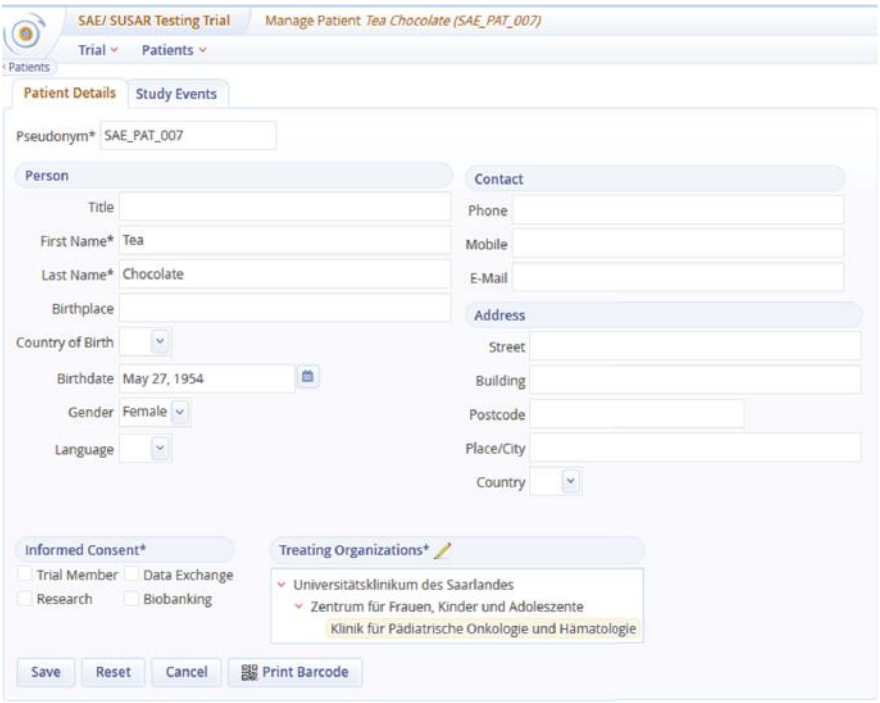


Figure 24: Patient's records

To navigate back to the patient list the user can either click on the 

button on the very left side of the navigation bar or use the Patients > Manage option.
To edit patient data or add new patient see chapter 2.3.

2.2.5.1 Navigation within Study Events

Study Events are located in the trial specific patients' folder. To enter data, the user has to select the respective event from the list on the left side (1) and open the CRF(s) to be edited which are displayed on the right side (2).

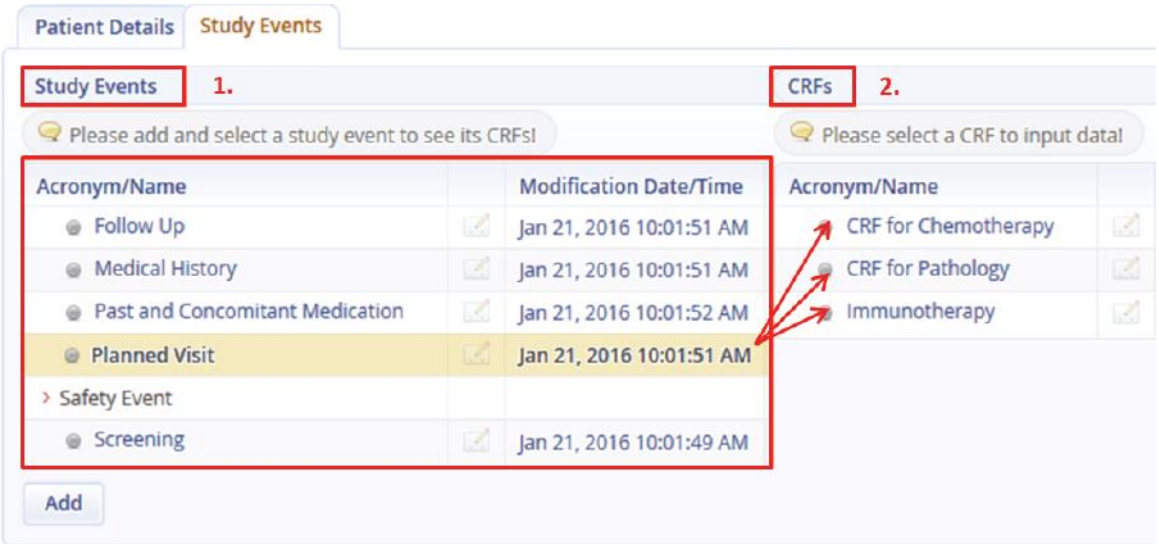


Figure 25: Study Event list

2.2.6 Navigation between CRF sections

There are two options to navigate between CRF sections:

a) Section Name (located on the top of the data entry forms): With these buttons the user is able to switch between the various sections of a CRF.

b) Click at the section name within the section list on the left side.

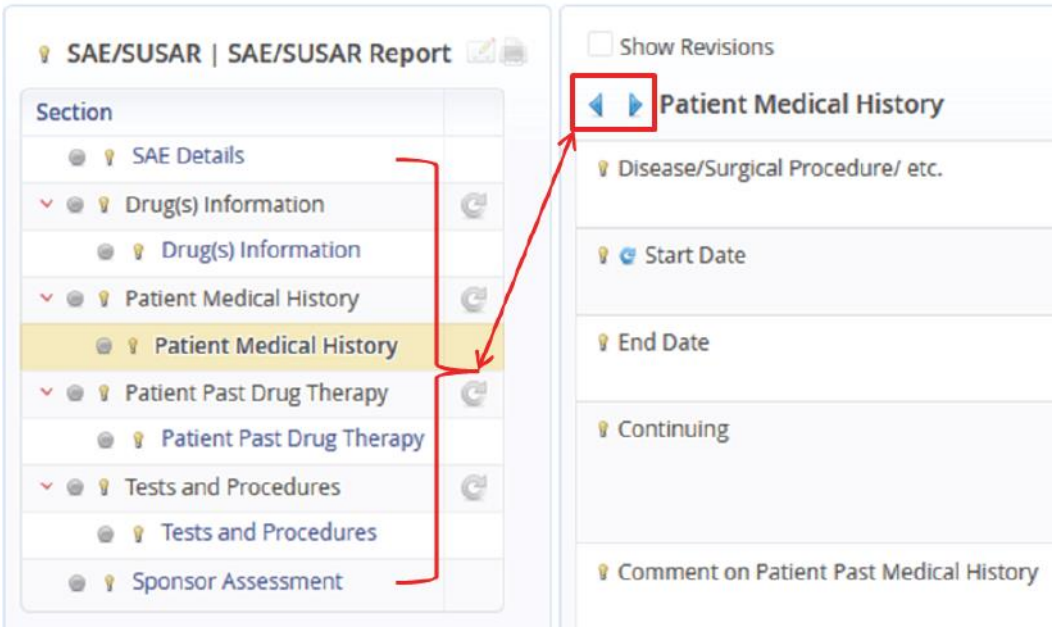


Figure 26: Navigation between CRF Sections

2.2.7 Navigation within lists

There are different kinds of lists in ObTiMA (user list, study events list, CRF lists…). All list entries are displayed in alphabetical order. You can reverse the alphabetical order by using the arrows right of the list headings (1.).

If the list comprises more than 10 entries, you can scroll the patient list using the arrows (2.) or numbers (3.) in the bottom line or you can extend the list to up to 100 entries by opening the number field (4.) on the right side in the bottom line of the list and chose the amount of entries you want to have displayed.

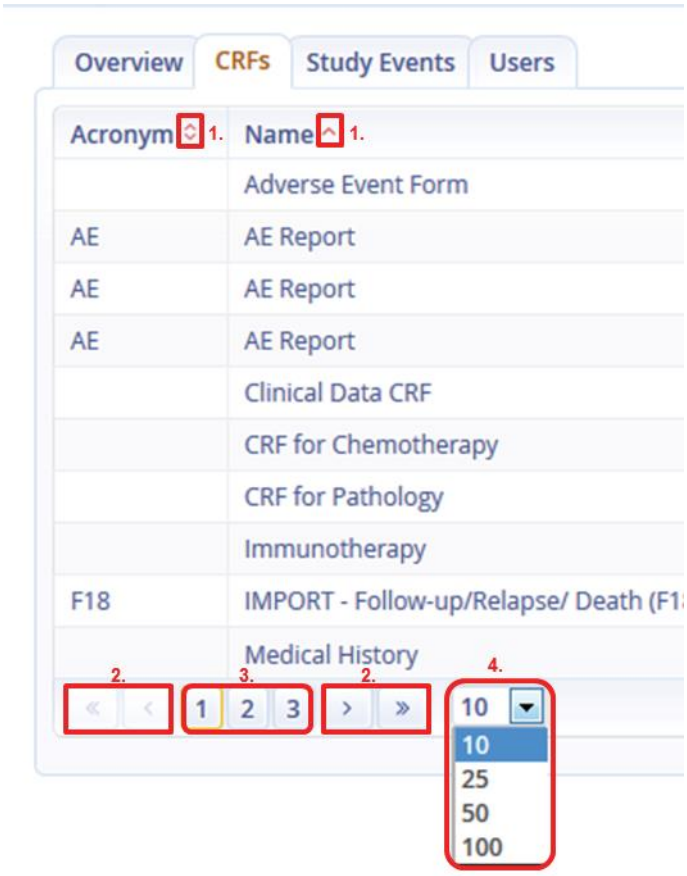


Figure 27: Navigation within lists

2.3 Data entry

2.3.1 General Information

The following instructions apply to the general entry of data:

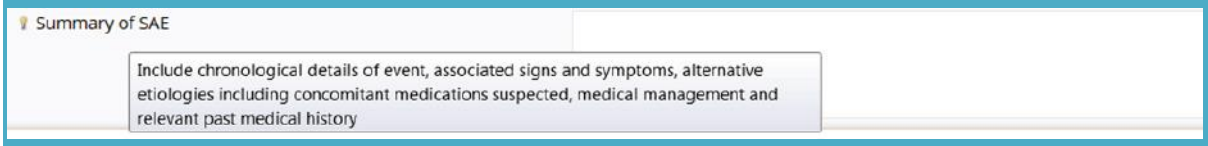
- Only investigators and designated qualified staff are allowed to enter data into the eCRFs.
- Data should be entered within the appropriate time frame according to the guidance in the protocol or contractual agreements.
- Do not abbreviate CRF entries.
- Do not use subscript or superscript characters when entering data into eCRFs.
- Symbols and special characters should not be entered in the EDC system.
- Ranges should not be entered into eCRF text fields (i.e. 1 - 3 hours).
- All text entries MUST be made in English.
- To add an additional comment to any field, click on the icon located on the right side to the respective answer field. A popup with a text field will open for entering additional comments. To save the entered comment, click at the “Save” but-

ton.

Note:

- Data must be saved as each eCRF page is entered. You will be prompted to save the page, if you attempt to move to the next page without saving data.
- If the system times out, unsaved data is lost.
- Fields marked with * are mandatory fields. CRF sections containing mandatory fields can only be saved after these fields have been completed. If you navigate away from the section without saving, the system will generate an alert message (see below).

- A yellow bulb ( ) to the left of a question indicates that there is an explanatory note to the question available by moving the mouse over the question (see example below).



2.3.2 Add new patient

- To add a new patient: Click on the “Patients” link in the navigation bar.
- A submenu opens; click on the ‘Create’ button, the patient data page opens.
- Complete the patient’s details (Minimum requirements are: pseudonym, first and last name as well as the existence of an informed consent).
- Click “Save” to populate the patient.

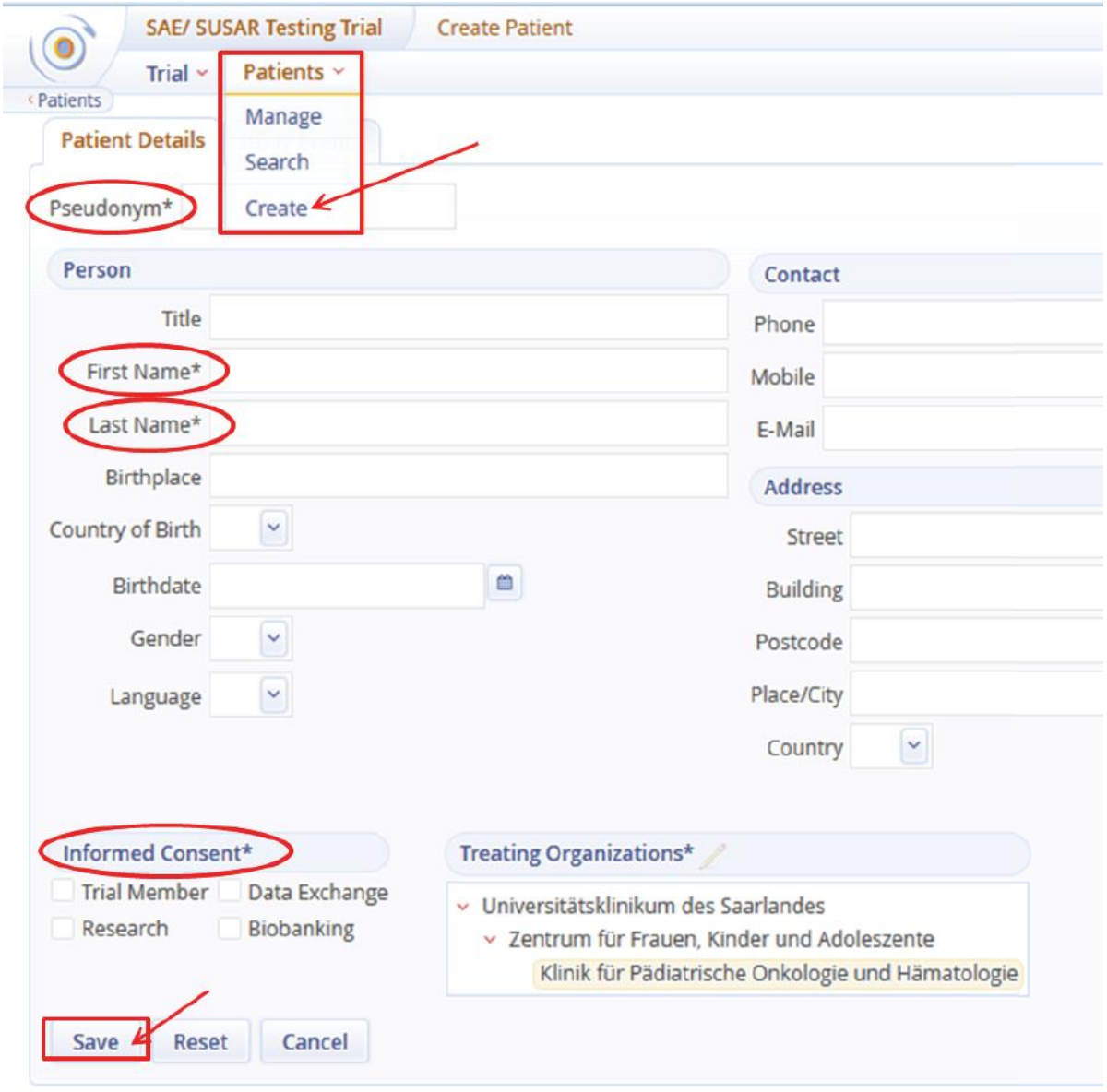


Figure 28: Add new patient

2.3.3 Search for a patient

How to search for a patient:

- Click on the “Patients” link in the navigation bar.
- A submenu opens; click on “Search” and enter the pseudonym of the patient you are looking for, and then left click on the search button below.

Figure 29: Search for a patient

Note:
You can only search a patient’s pseudonym and not the full name!

2.3.4 Patient specific barcode/ QR (quick response) code

- Click on the “Print Barcode” button on the patient details page to print out barcodes or QR codes for a patient.
- The patient specific barcode and QR code will be displayed in a new window, select “Print Barcode” or “Print QR Code” to create patient specific barcode/ QR Code labels to mark e.g. patient’s records, sample containers, other patient specific devices, medication….

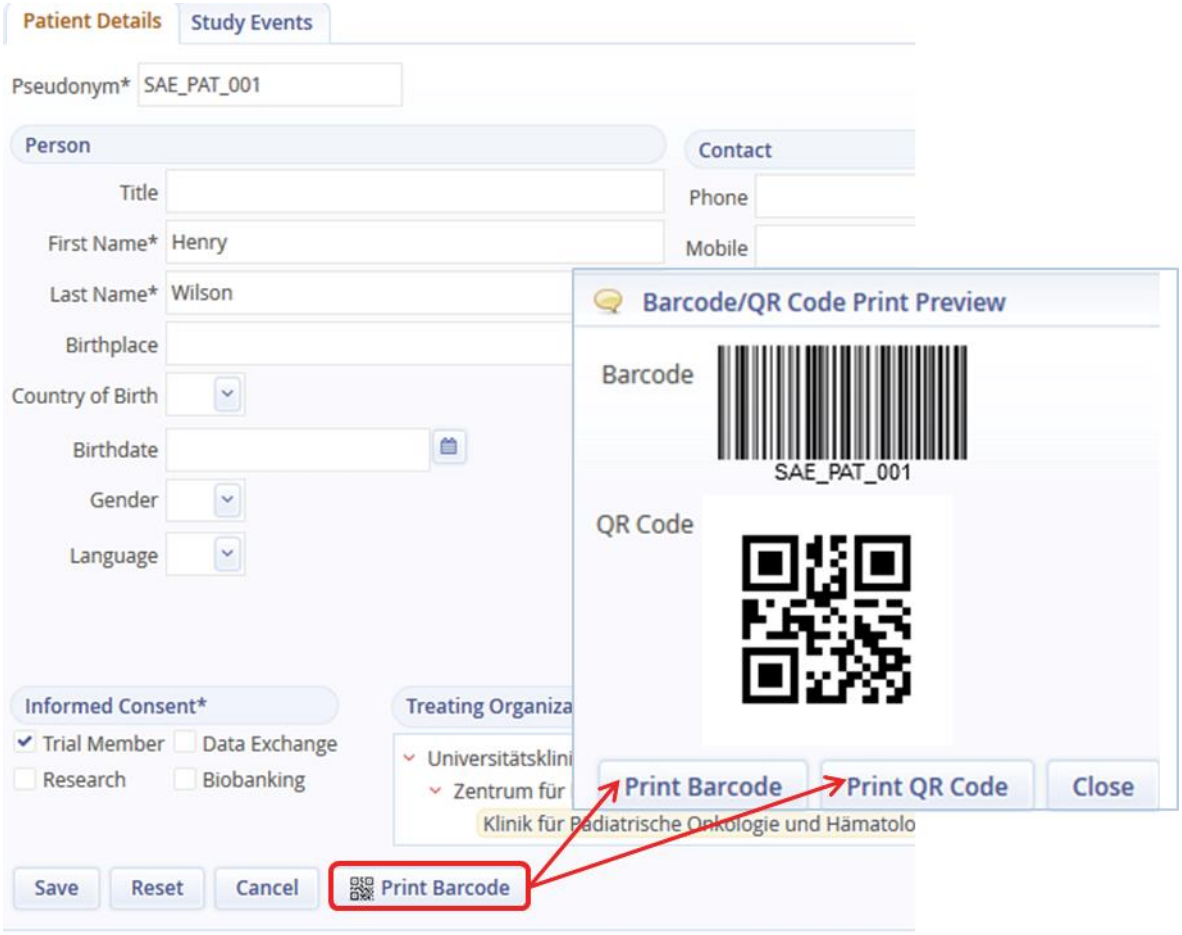


Figure 30: Barcode / QR code

2.3.5 Patient Data Entry

- Open patient documentation under Patients > Manage (1.).
- Select the respective patient you want to view/ edit from the list (2.).
- A new window will open containing the patient documentation (3.).
- Patient's full name will be displayed on navigation bar on the upper left side next to the trial name (4.).

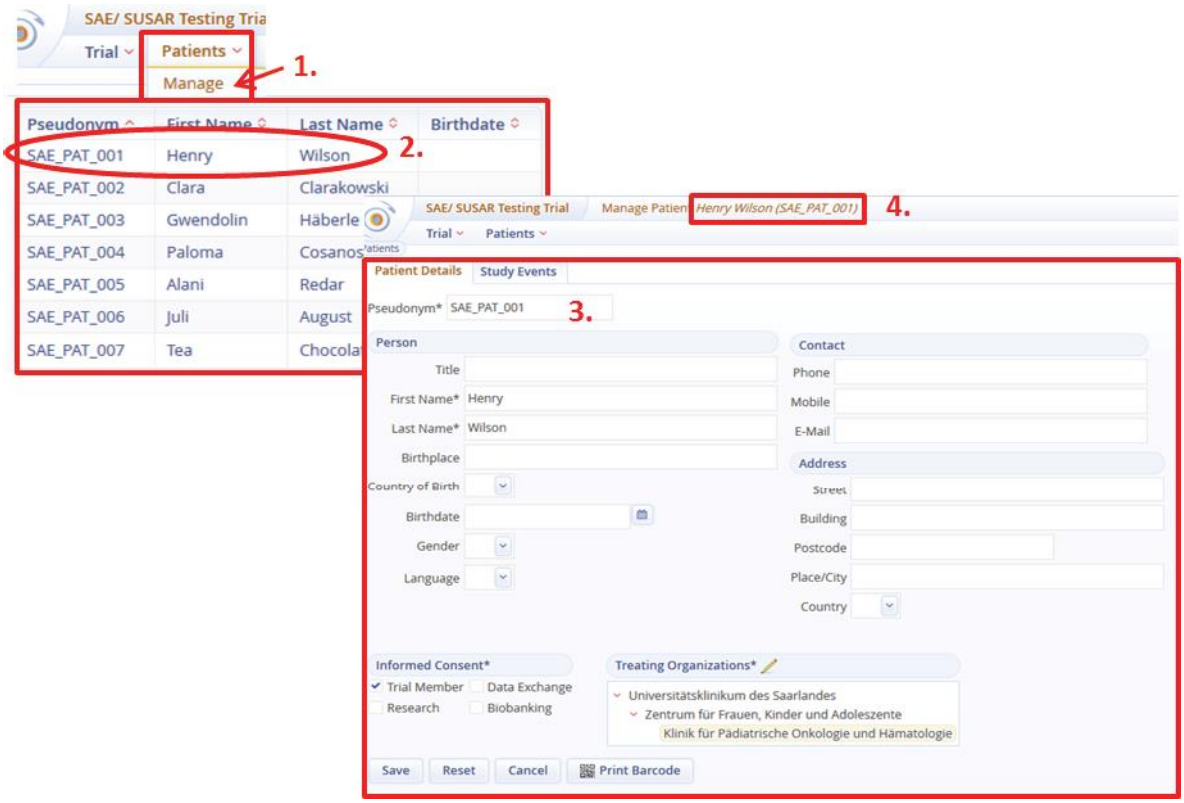


Figure 31: Open patient data entry Page

- Click on the document header (e.g. Patient Details, Study Events (1.)) and either start data entry straight away (Patient Details) or open the Study Events menu and select the study event you need to work with from the list on the left side (2.).
- To open a CRF within the selected study event click on the CRF name in the CRF list on the right side (3.) and start data entry (4.).

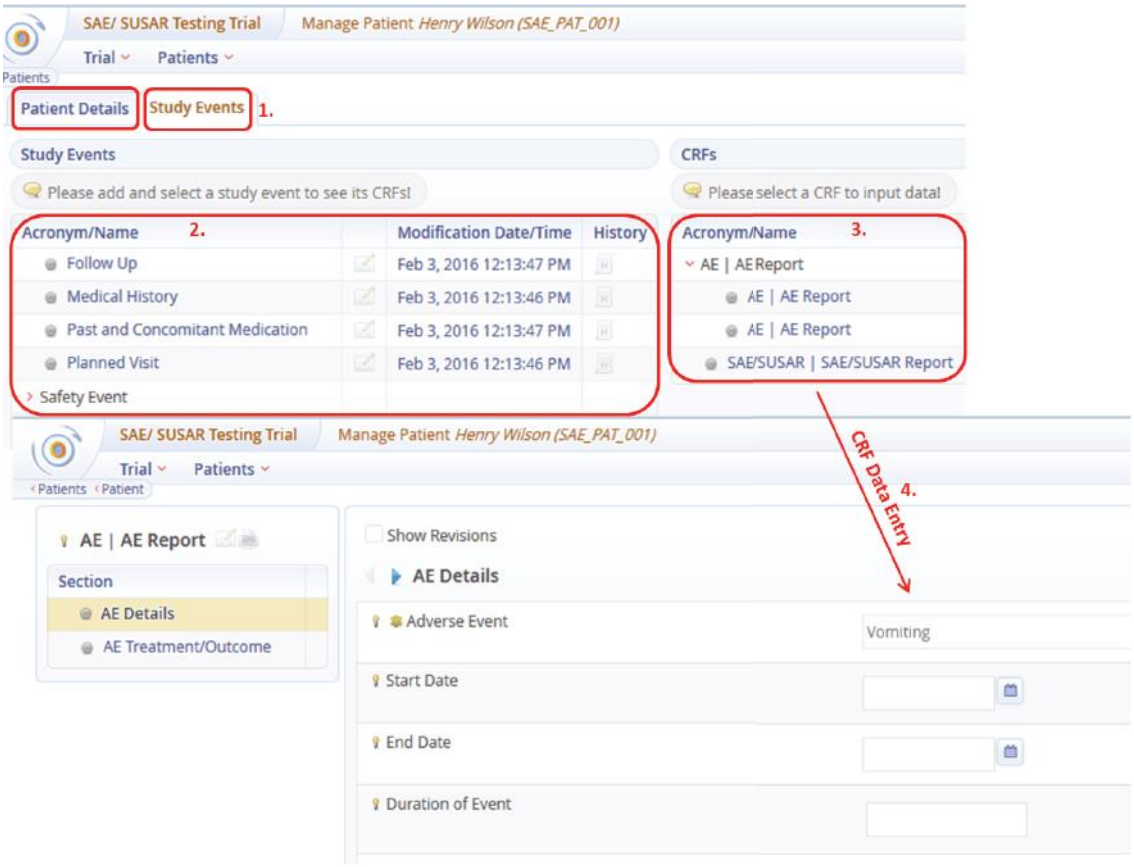


Figure 32: Data Entry

– After you have entered information into CRF data fields (1.), click the ‘Save’ button (2.) located on the lower left part of the CRF page to preserve changes. The validation grade on the right side of the questions will automatically be set to ‘🟡’ (Data entered but not yet verified) (3.). For further information regarding data validation see chapter 2.3.7.

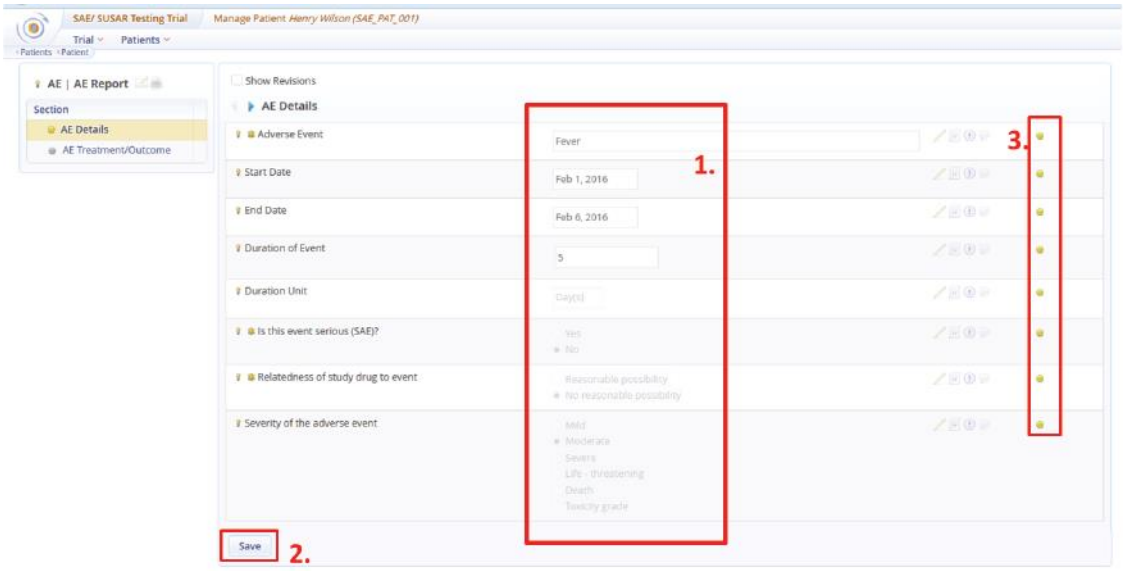


Figure 33: Data entry completed

- If you navigate away from the section without saving, the system will generate an alert message notifying you that you are about to proceed without saving your changes.

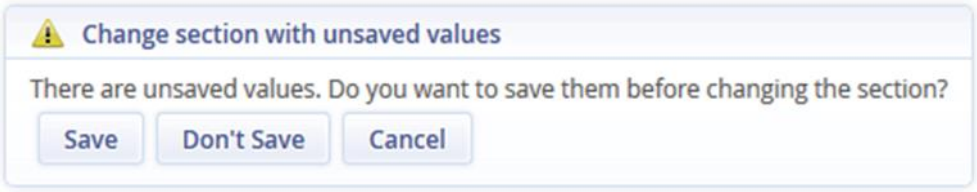


Figure 34: Alert message: Unsaved values

Note:
- Some forms and fields have edit checks programmed to validate the data on the form or to cross-check against other forms. For this reason, it is recommended that you complete forms in order to avoid generating unnecessary system queries.
- The data entry fields will display the 'never touched' icon (●) until data is entered, saved, and accepted (see also chapter 2.3.7).

- If you want to edit already saved data click on the edit icon (1.). A new window opens where you can enter the new value or add furhter information (2.) and additionally, you have to give a reason for changing (3.).

– Click “Save”, to save your changed/ updated value or cancel to keep the original value (4.).

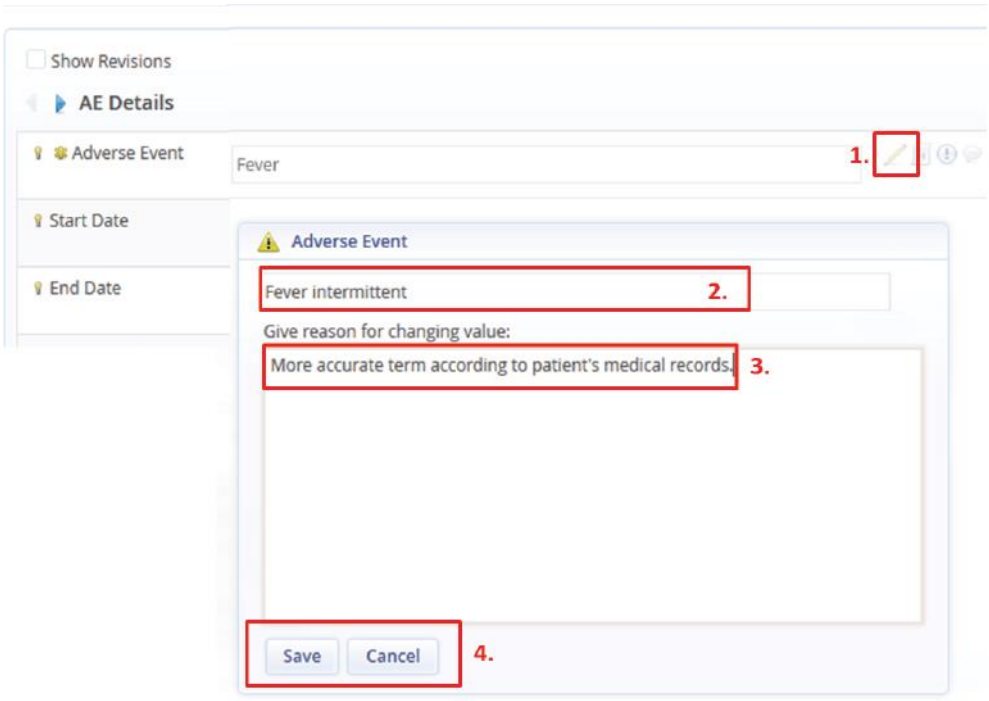


Figure 35: Edit existing value

2.3.6 Data unknown or not available

To indicate that data is unknown or not available click on the ‘add comment’ icon located on the right side to the respective answer field (1.). A popup with a text field will open. Enter a comment (2.) and answer ‘Yes’ to the question ‘Value unknown or not available’ (3.), then save your entries (4.).

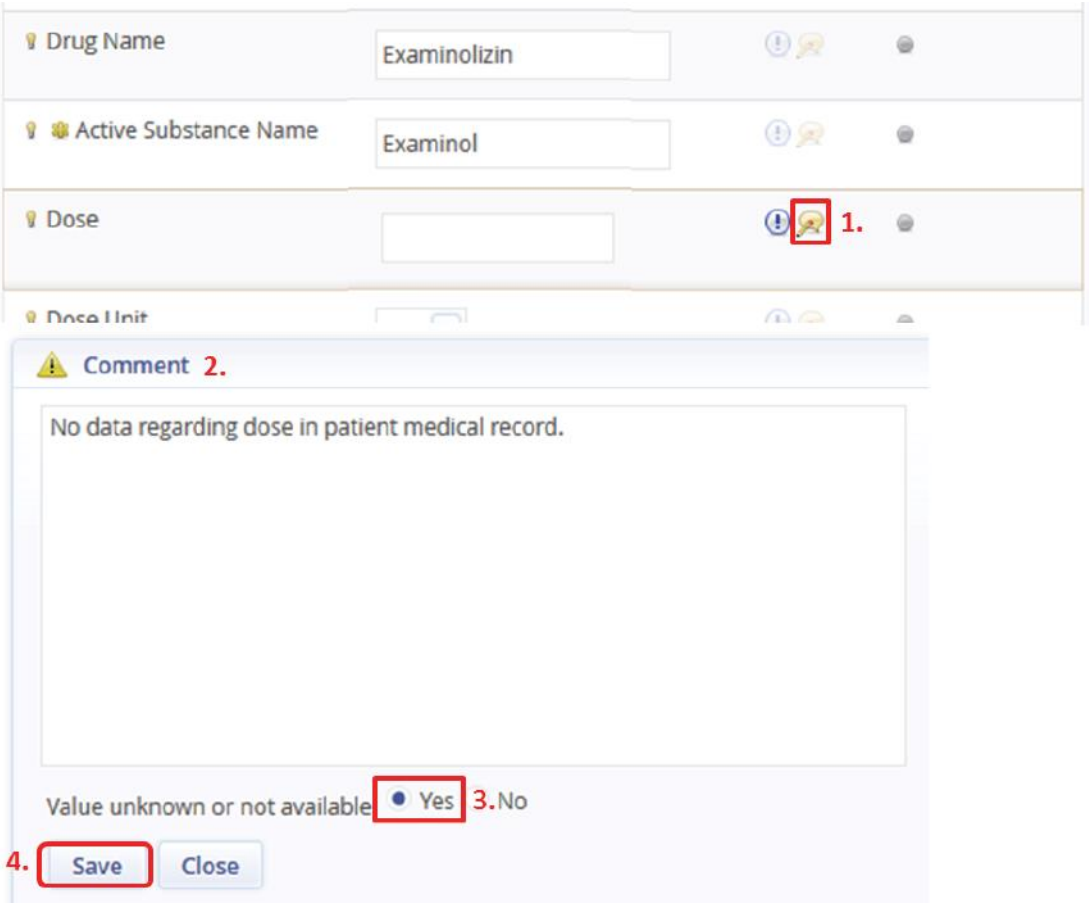


Figure 36 Mark data unknown/ not available

Once you have marked a data value as unknown or not available, the data field remains empty and data entry is blocked.
If later on more precise data becomes available, click on the 'enter comment' icon located on the right side to the respective answer field (1.).
Enter a comment (2.) and answer 'No' to the question 'Value unknown or not available' (3.), then save your entries (4.). Now you can enter the more precise data in the data field (5.) and save your entries.

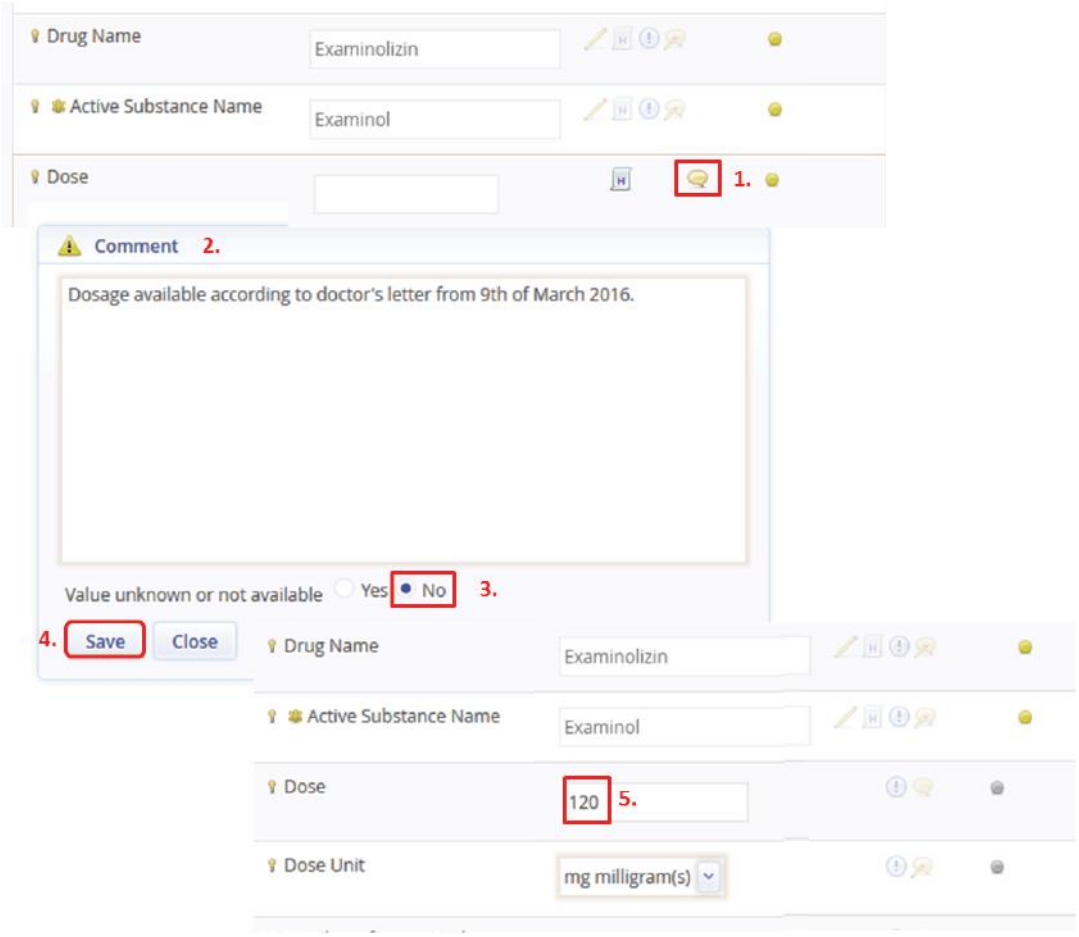


Figure 37 Revise data entry

2.3.7 eCRF entry field types

2.3.7.1 Free text field

Enter any kind of free text, also numbers are possible.

All entries need to be done in English.

Figure 38: Text field

Note:

- Do not use abbreviations, subscript or superscript characters nor symbols or special characters.
- Ranges should not be entered into eCRF text fields (i.e. 1 - 3 hrs).
- All text entries MUST be made in English.

2.3.7.2 Number field

Only numbers can be entered. Decimal places must be separated using a point, not a comma. Number fields can be limited, e.g. the number must be greater than 0 and smaller than 200. Additionally, there are many possibilities of different measurement units like percent, gray, cm, etc. which are either predefined or can be chosen from a drop down menu.

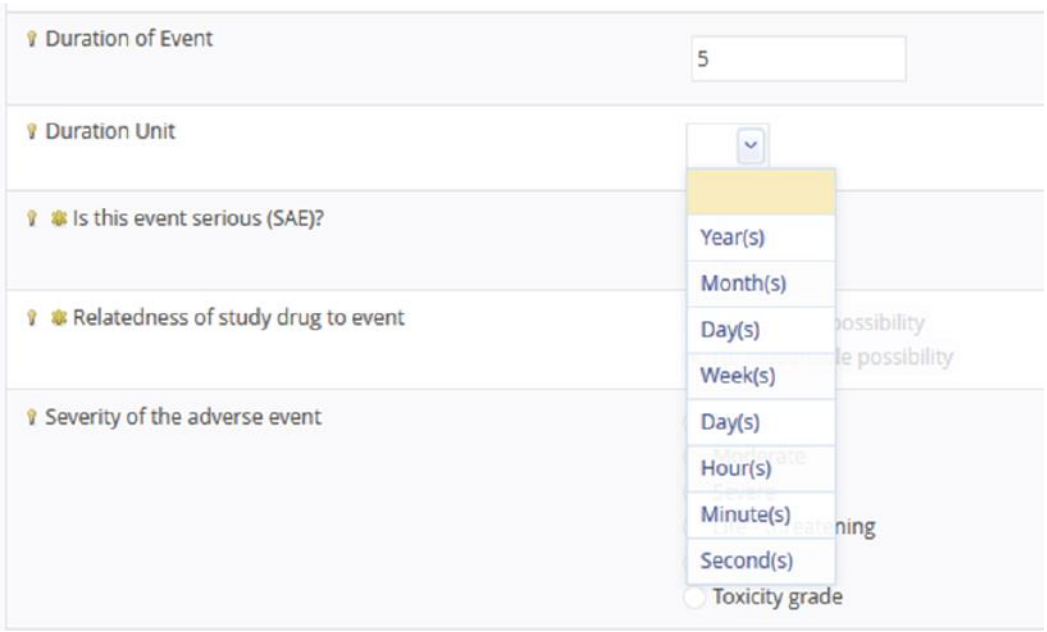


Figure 39: Number field

If text instead of a number is entered an error message will be displayed:

Figure 40: Error message number field

If entered number is out of an expected (predefined) range, an error message will be displayed:

Figure 41: Value out of range message

If a value is actually outside the expected range, then you have to enter a reason.

- Click on the “Mark value abnormal” icon (1.) to the right of the data field.
- A popup opens. Enter a reason, why the value is abnormal (2. + 3.).
- Click “Save” button (4.).

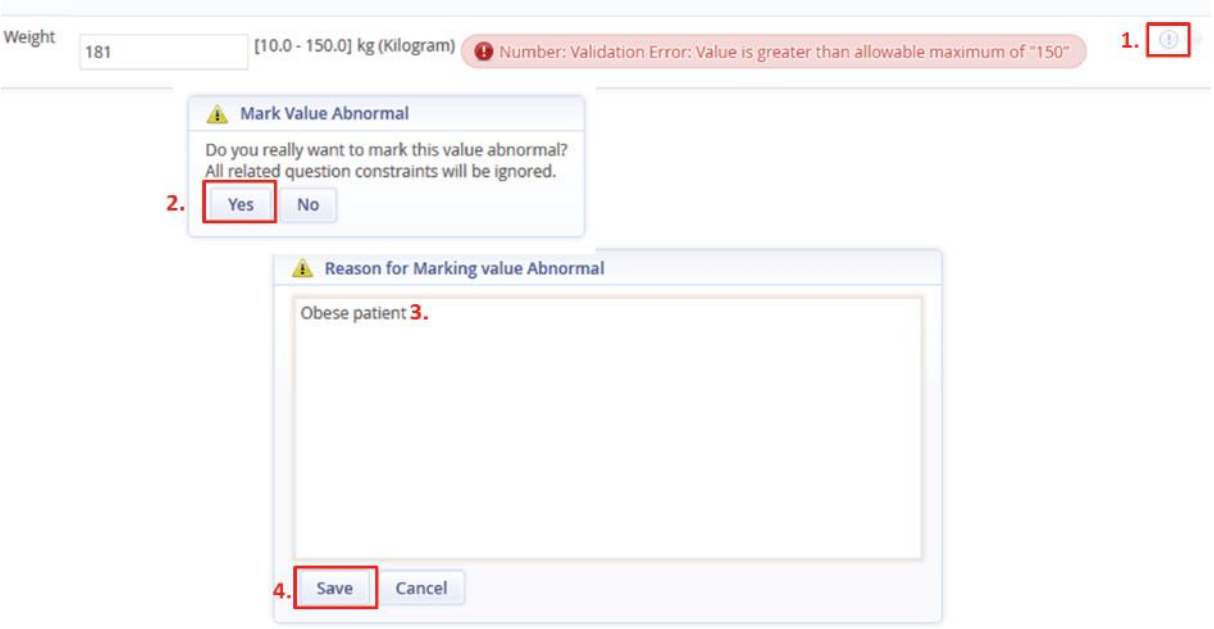


Figure 42: Reason for “Value out of range!”

“Mark value abnormal” icon is replaced by “Value marked abnormal, see reason” icon. Now, it is possible to save a value that is out of the defined range.

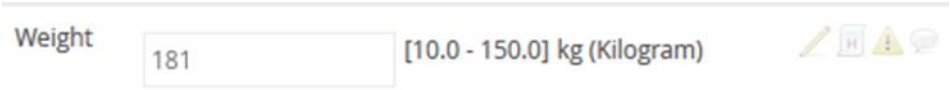


Figure 43: Value out of range entered

2.3.7.3 Date field

Dates have to be selected in the calendar window. All dates are in MON DD, YYYY format (e.g., 10th of April 2013, would be entered Apr 10, 2013).

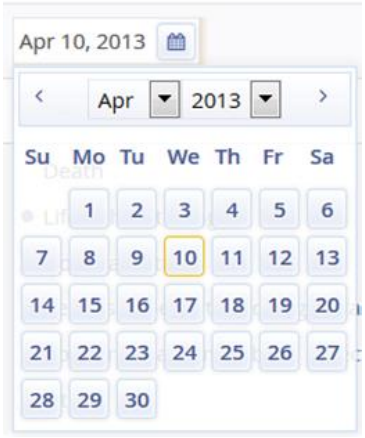


Figure 44: Date field

If the date is unknown or only partially known, open the comment field next to the date field and enter a comment, e.g. date unknown/ partially known. Then set the 'value unknown/ not available button' below the comment field to 'yes' and save your entries.

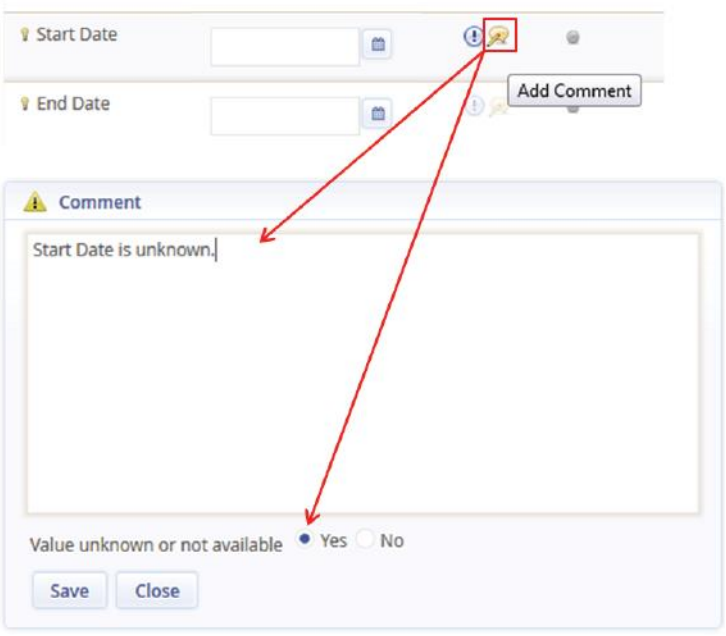


Figure 45: Date partially known/ unknown

2.3.7.4 Select one menu

Open the menu and select the answer. Only one answer can be selected!

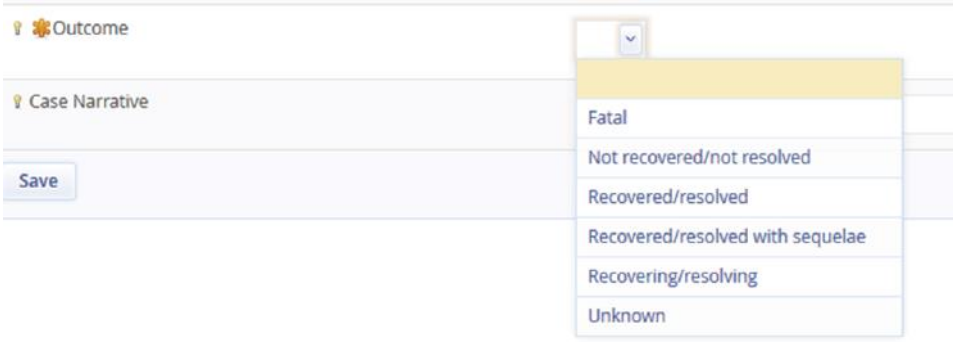


Figure 46: Select one menu

2.3.7.5 Select many menu

Select many answers by using the “CTRL” key and the left mouse button to select several answers.

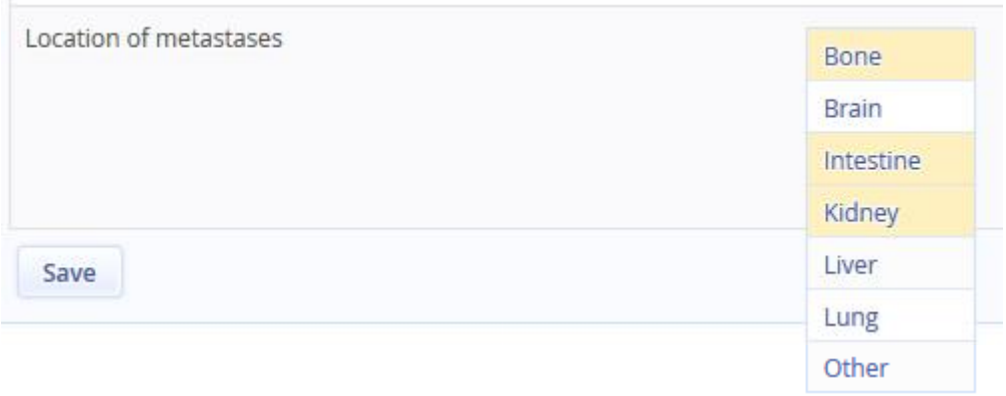


Figure 47: Select many menu

2.3.7.6 Check boxes

Check all boxes that apply.

Figure 48: Check boxes

Some questions offer the possibility to select all answers at once. Click the “Select all” checkbox and all answers will be marked automatically.

Figure 49: Select all checkbox

2.3.7.7 Radio button

Select the single best choice by clicking the adjacent circle.

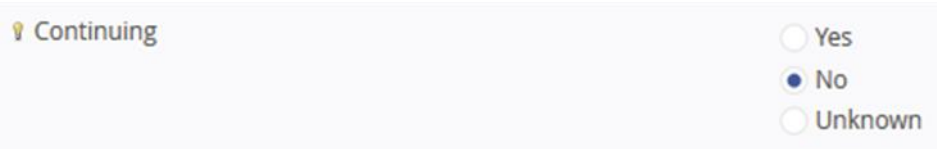


Figure 50: Radio buttons

2.3.7.8 Hidden questions

To make the data entry process easier and quicker, many questions are displayed only when a specific answer is given, and are hidden otherwise. This is only applicable for checkbox or radio button data entry fields.

As shown in the example below, the “If other, please specify” will only be displayed after selecting “other” from “Location of Metastases”.

Figure 51: Hidden questions

2.3.7.9 Saving of entered data

After completion of the current section, click the “Save” button beneath the last question. Your entries will be checked. During the saving process, the ObTiMA interface is blocked. After finishing the saving process, you will be able to move to the next section or patient.

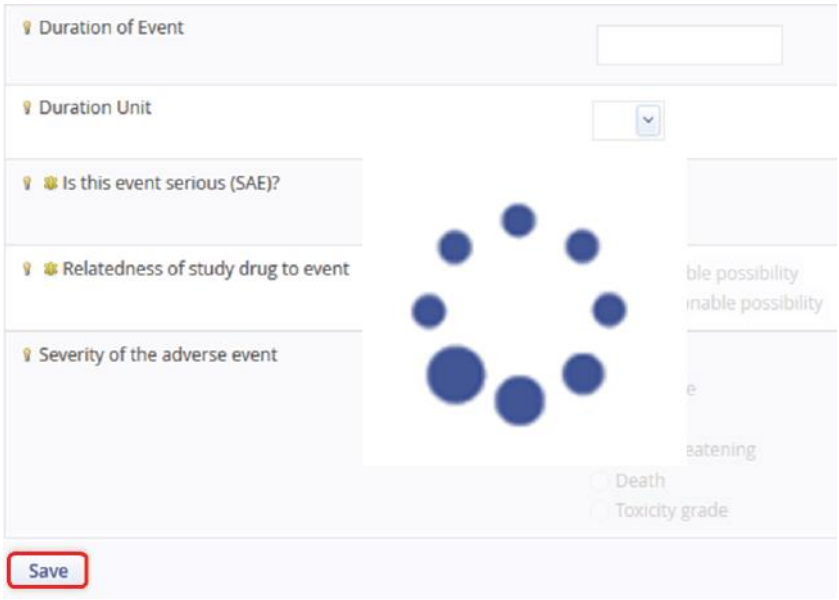


Figure 52: Saving of entered data

If you try to leave a CRF section or close the CRF without saving your entered data an error message pops up:

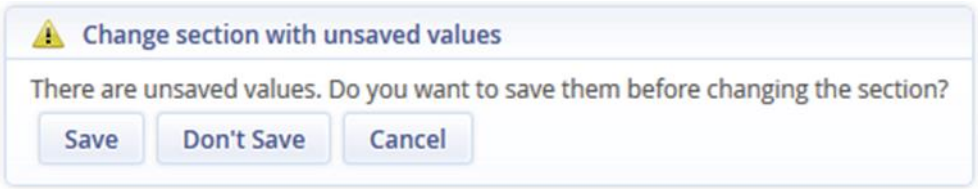


Figure 53: Error message unsaved value

2.3.8 Validation

The current status of data entry progress/ verification is color – coded. The color coding is applied to each level of data entry (data field < CRF section < CRF < study event). The color code is defined as follows:

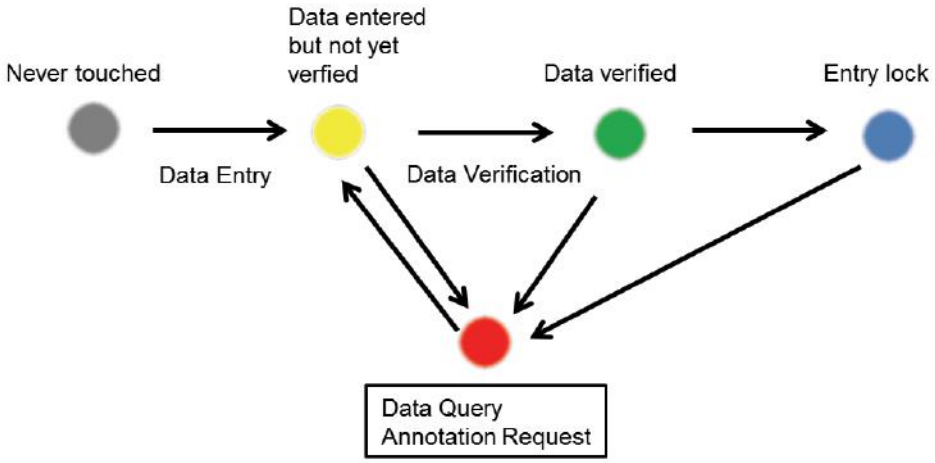


Figure 54: Data validation procedure – Color Code

After data has been entered and saved by authorized local site staff, the validation status will be automatically set from grey (never touched) to yellow (data entered but not yet verified). Further validation procedures can only be carried out by the sponsor/ trial chairman and/ or their designated delegates. If the sponsor/ trial chairman and/ or their designated delegates raise a query and/or request further annotation, the validation icon of the respective data entry field will be automatically set to red (data query/ annotation request). After query solution by authorized local site staff the validation status will automatically turn to yellow and is ready for renewed verification by sponsor/ trial chairman and/ or their designated delegates.

The colored icons are displayed on the right of the respective data entry field in the data entry level and on the left in the study events, CRF and CRF sections level.

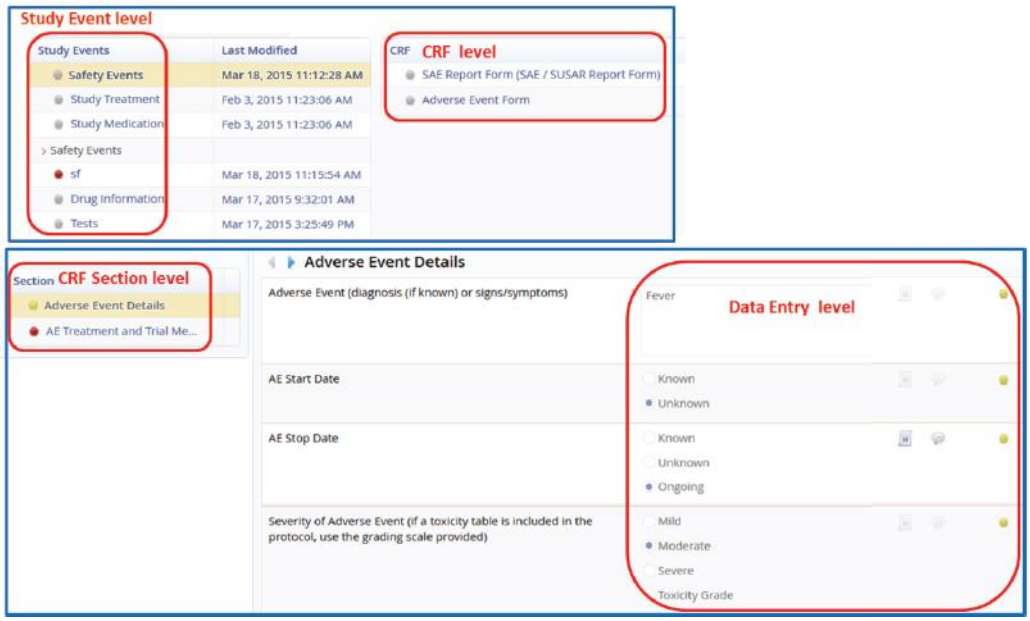


Figure 55: Location of validation icons

The validation status of next higher level will only be changed after the complete data entry/ validation of the previous date entry level has been carried out (data field < CRF section < CRF < study event). E.g. the validation grade of a study event will only turn from grey (never touched) to yellow (data entered but not yet verified) if data entry in all CRFs within this study event have been finalized. If there are different validation grades in the same level, the validation status of the next higher level corresponds to the lowest validation grade in the previous level. E.g. If in a data entry level there are various data entry fields marked with green (data verified), yellow (data entered but not yet verified) and grey (never touched),respectively, the validation icon of the corresponding CRF section level is grey.

2.3.9 Audit Trail

The Audit Trail keeps track of certain actions in the current study. It does this by recording relevant user activities (such as who logged in and when) and storing this information in the form of a log.

Authorized users are able to view the Audit Trail. To access the Audit Trail click on the “Show history” (1.) icon located to the right of the data field, the corresponding audit log is displayed (2.). To close the audit log click “Close” at the bottom left corner of the log (3.).

Data Fields

Any changes that are made to data fields in a CRF are tracked:

- Action that was performed on the data field (old and new values, and why the change was made to the data, any comments related to the data field)
- Date and time of action
- User who performed the action (editor)
- Marked abnormal and no value

The more recent data entry/ changes are at the top of the log.

Figure 56: Audit trail of selected data field

Sections

The Audit Trail tracks the following changes that are made to sections in a CRF:

- date and time of action
- user who performed the action

To access the Section Audit Trail click the 'Show revisions' checkbox located in the CRF page on the upper left corner of the CRF.

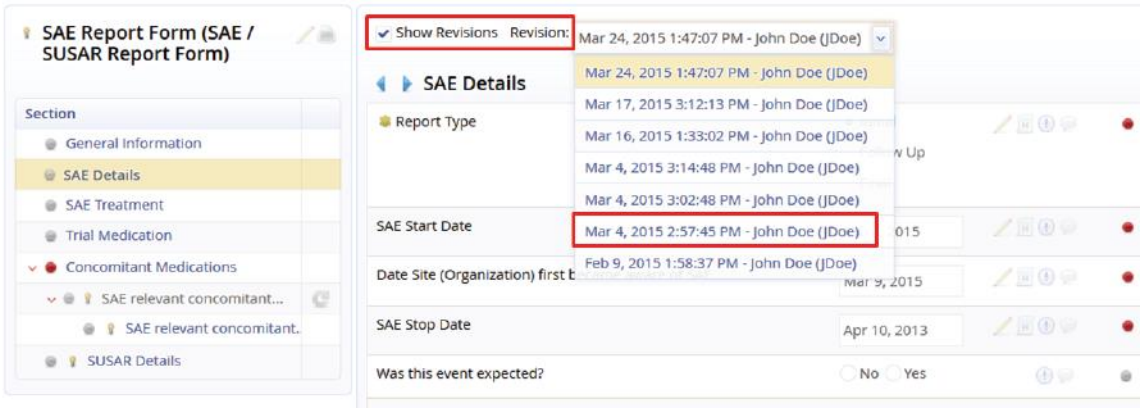


Figure 57: Audit trail sections

After the selection of a revision date from the list, the completion status of the data

entry fields of the respective CRF section at the time of the chosen revision date is displayed. These fields are not editable! To close the section specific audit log and return to the latest data entry status click the ‘Show revisions’ checkbox on the upper left corner of the CRF page again (check mark will be removed).

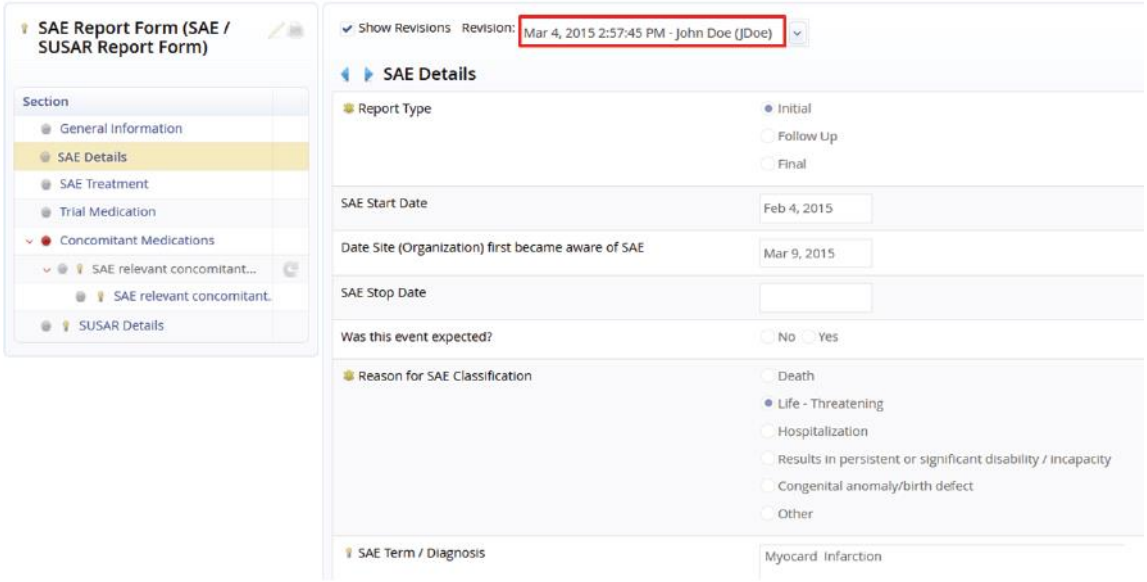


Figure 58: CRF completion status on specific date

3 Manage Data Entry Forms

3.1 Add Study Event(s)

As some events can also occur more than once, there is the possibility to add study events to a patient’s documentation.

To add a Study Event click on the ‘Add’ button in the Study Event folder of a certain patient. A list with available study events will be displayed. Select the study event(s) you need to work with from the list and click the “Add Selected” option at the bottom of the list.

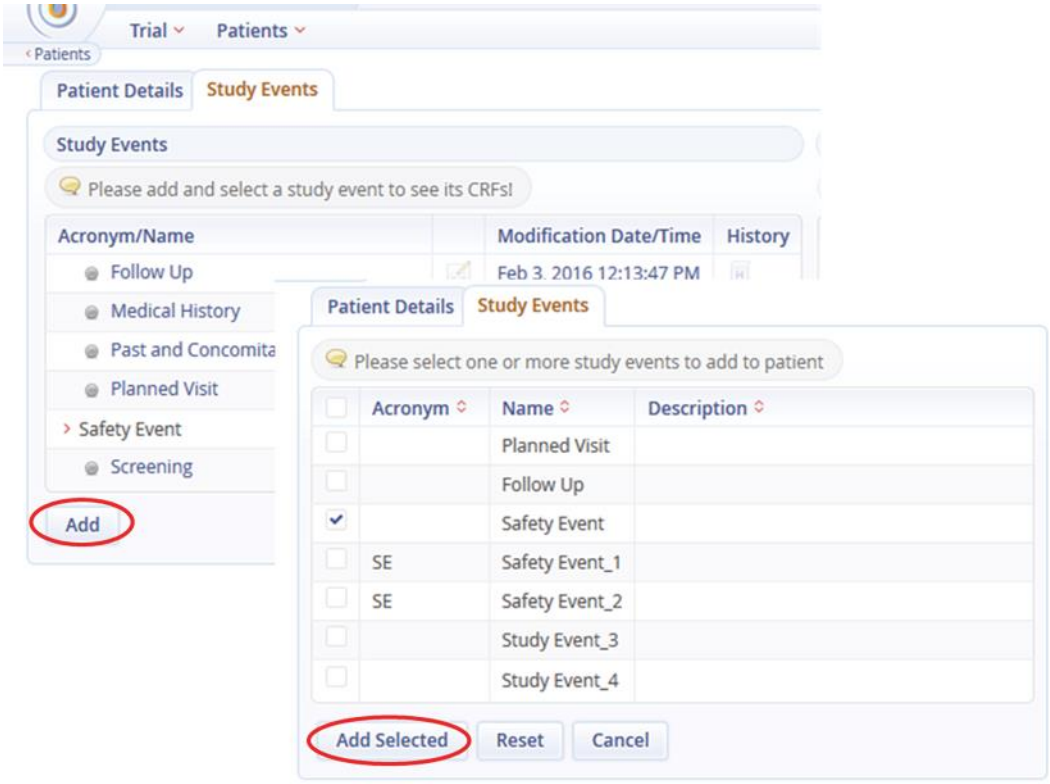


Figure 59: Add Study Event

Once you have added a study event to a patient's folder, only the sponsor/ administrator can remove it. So please contact the sponsor/ administrator to discard study events that are not required and/ or have been added by mistake.

3.2 Edit Study Event Name

You can assign your own name to each study event by clicking on the card – pencil icon located to the right of the respective study event in the patient's study event menu. A window opens where you can enter your study event term of your own choice. Click 'Save' to complete your renaming.

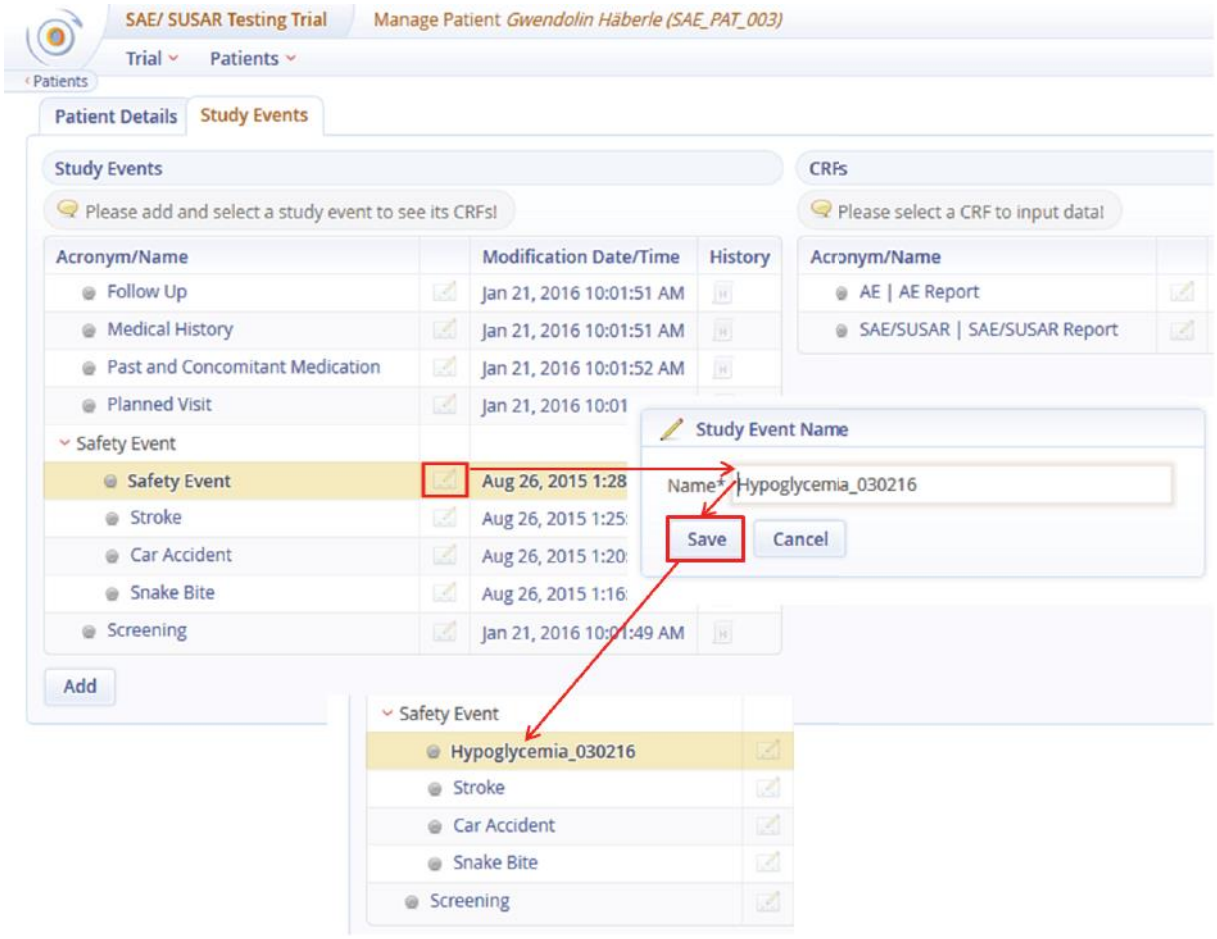


Figure 60: Edit Study Event name

3.3 Add/ Delete CRF

The “Repeat CRF function” enables you to use the same kind of CRFs multiple times. Open the study event folder and select the study event, which contains the CRF you want to duplicate. Click on the repeat button located to the right of the respective CRF in the CRF list within selected study event (1). After confirmation of the CRF replication (2), the CRF will automatically be added to the study event (3).

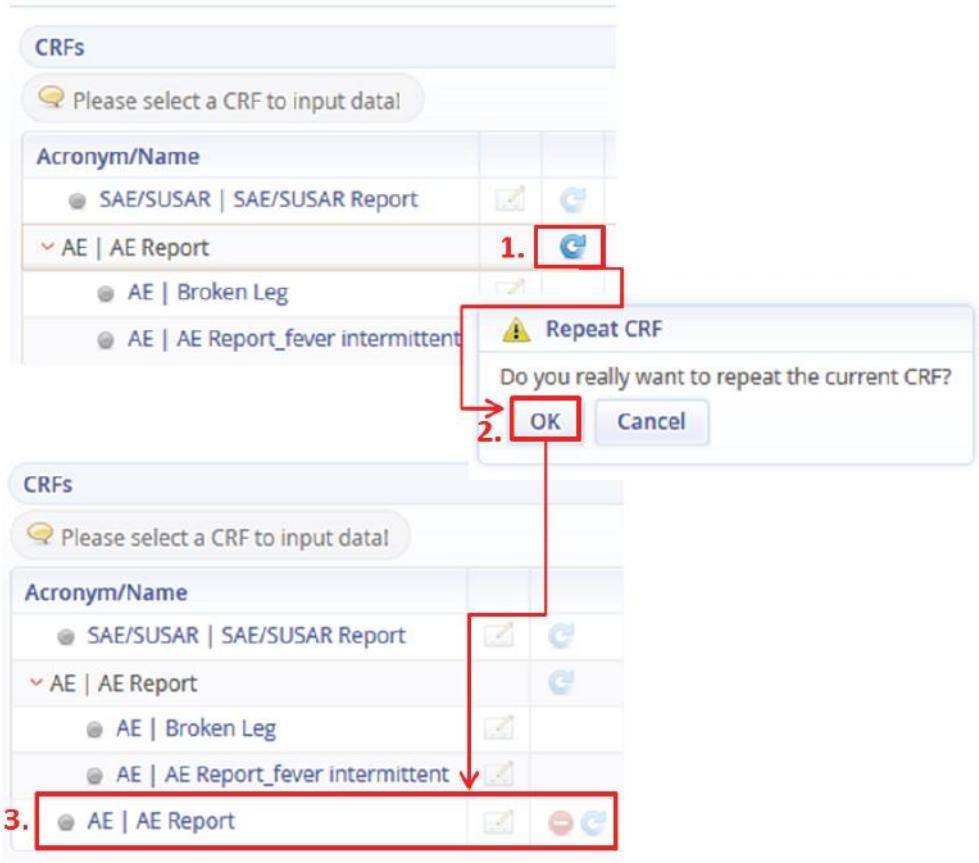


Figure 61: Add CRF

To remove a CRF from the study event by using the delete button to the right of the CRF name.

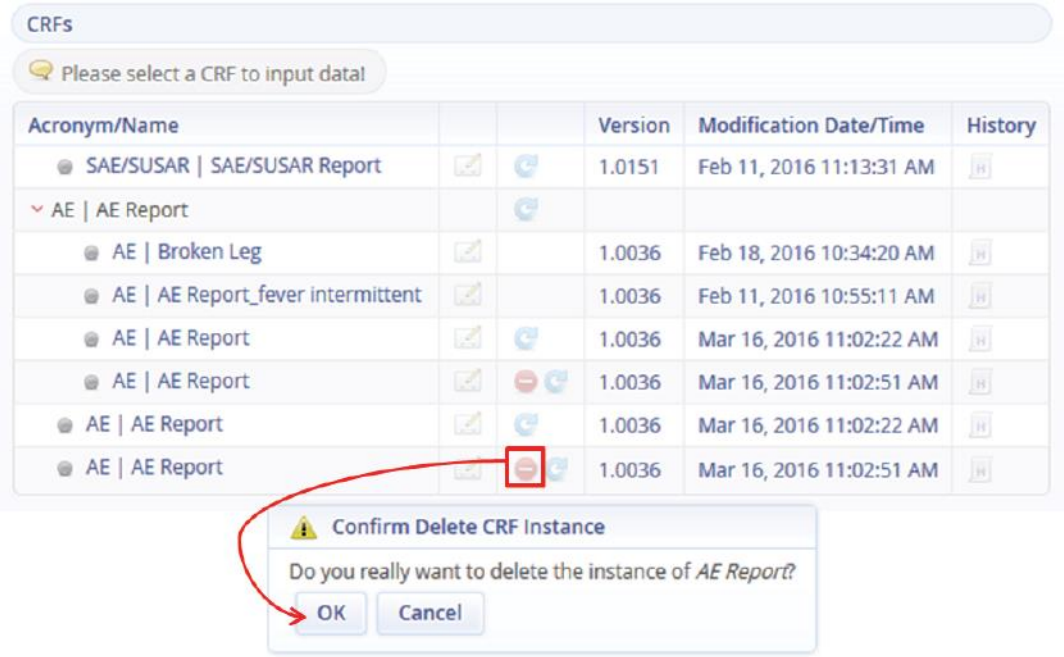


Figure 62: Delete CRF

Note:
- Deletion of a CRF is only possible as long as not data has been entered and saved.
- Once you have saved data in a CRF, only the sponsor/ administrator can remove it. So please contact the sponsor/ administrator to discard the CRF that is not required and/ or have been added by mistake

3.4 Edit CRF Name

You can assign your own name to each CRF by clicking on the card – pencil icon located to the right of the respective CRF. A window opens where you can enter your CRF term of your own choice. Click 'Save' to complete your renaming.

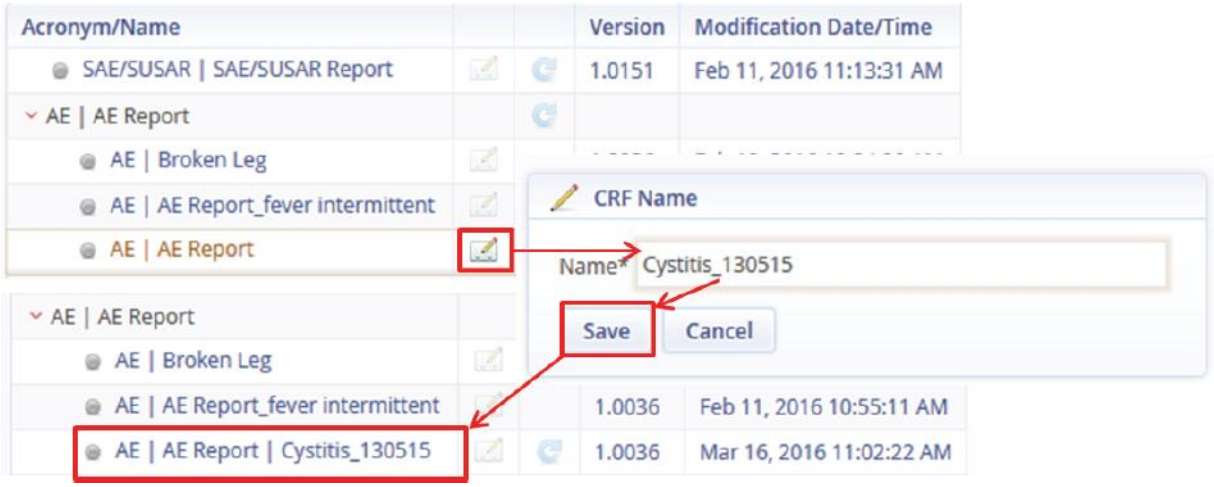


Figure 63: Edit CRF Name

3.5 Print CRF

To print a CRF, open the respective CRF you want to print and click on the printer icon located next to the CRF name on the upper left side of the CRF. The print view of the selected CRF together with the print menu will be displayed in a new window.
After print out of the CRF the window will be closed automatically.

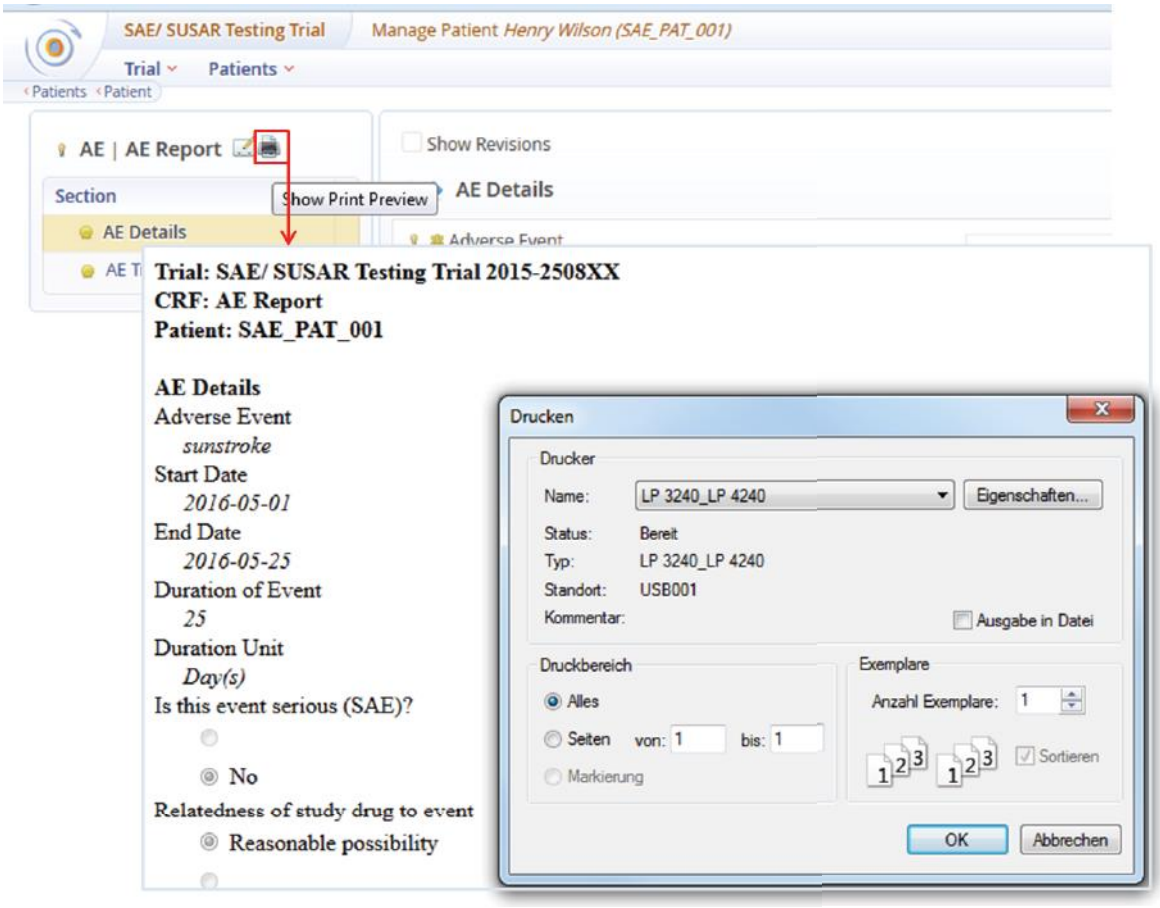


Figure 64: Print CRF

4 Glossary

Audit Trail / History: System feature that maintains a historical record of key actions related to a patient that has been taken on the ObTiMA database.

CRF (Case Report Form): An electronic document designed to record all of the protocol required information to be reported to the sponsor/ trial chairman on each trial subject

Delete: A delete action completely removes the information from the ObTiMA system. Deleted information cannot be restored, although the audit log tracks the deletion action.

Data Item: A single question in a CRF. Items have metadata attached to them. Items can have multiple edit and/ or validation checks attached to them.

Patient: A person who participates in a study.

Pseudonym (Person ID): The unique identifier for a patient that references the patient with-

in a study and also across all studies in the ObTiMA system.

Roles: Categories for users in ObTiMA that determine the tasks available to them in the system. Each user is assigned at least one role in the ObTiMA system. This role is a accompanied by certain rights and obligations depending of the user's qualifications.

Organization: Location where the study is taking place.

Study: In ObTiMA, a clinical trial or clinical research project, including all the metadata and data for it.

Study Event: A visit or encounter in the study where data is captured or created. A Study Event packages one or more case report forms (CRFs).

User: Person using the ObTiMA software. A user can have one or more roles in one or more studies or sites.