DATA ENTRY GUIDELINES

1. Log in to eCRF

Start a web browser on your computer and enter the link

for the demo instance of the eCRF: https://g-lacc-demo.xclinical.net/
(for training purposes only, do not enter real patient data)

for the productive instance of the eCRF: https://g-lacc.xclinical.net/

The start page of the eCRF is displayed. Enter your username and password to access the eCRF.

Figure 1: Enter username and password

2. Change password

To change the password without being prompted by the system go to *'Users'* on the left hand side navigation bar, click on your name in the list and then go to *'Change password'*. Enter your old and new password and log in again.

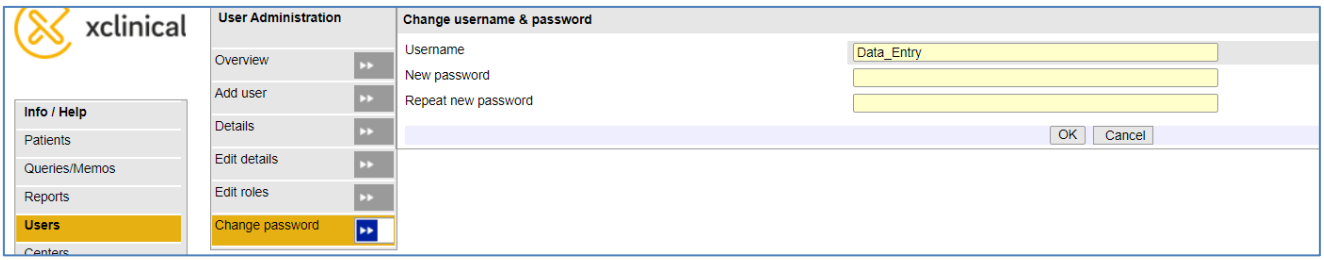

Figure 2: Change username and password

The password must have a length of at least 8 characters and must contain upper case, lower case, special characters (e.g. ?, !, *) and digits. It must not have been used by you before.
If you have forgotten your password, click on *'Forgot your password?'*. If your email address is stored in the MARVIN user administration, a new password will be sent to you.

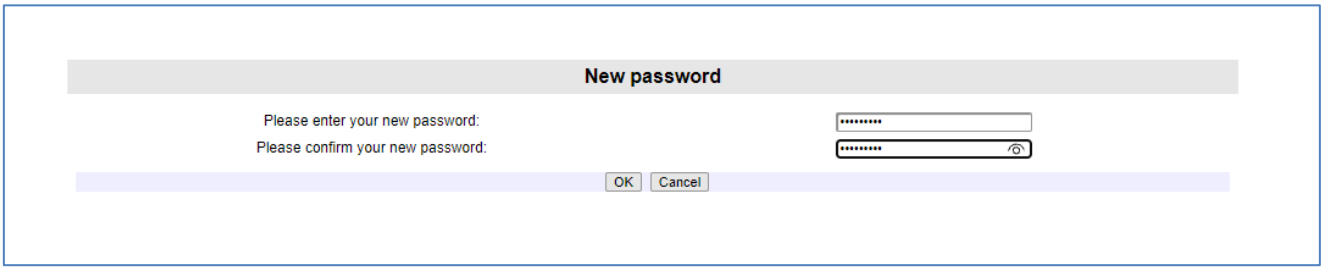

Figure 3: New password

3. Create a new subject

To create a new subject in the eCRF, go to *'Patients'* on the left hand side navigation bar. A list of already existing subjects is displayed.

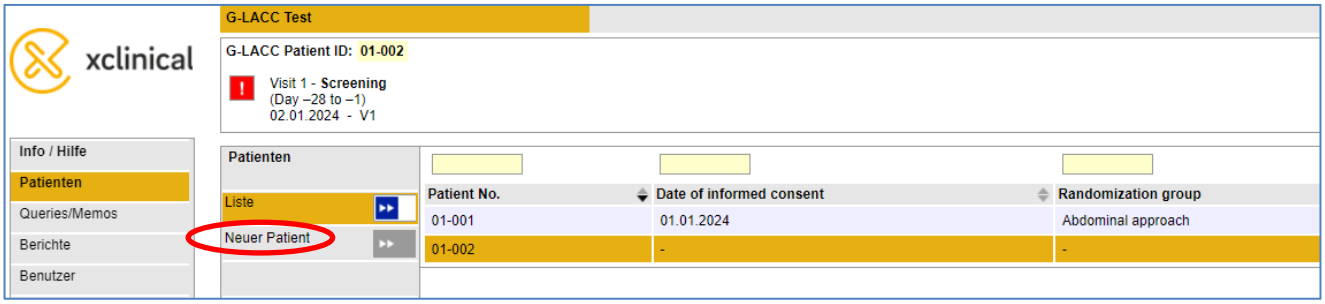

Figure 4: Add new patient

Go to *'New Patient'*. The first form of the patient is displayed.

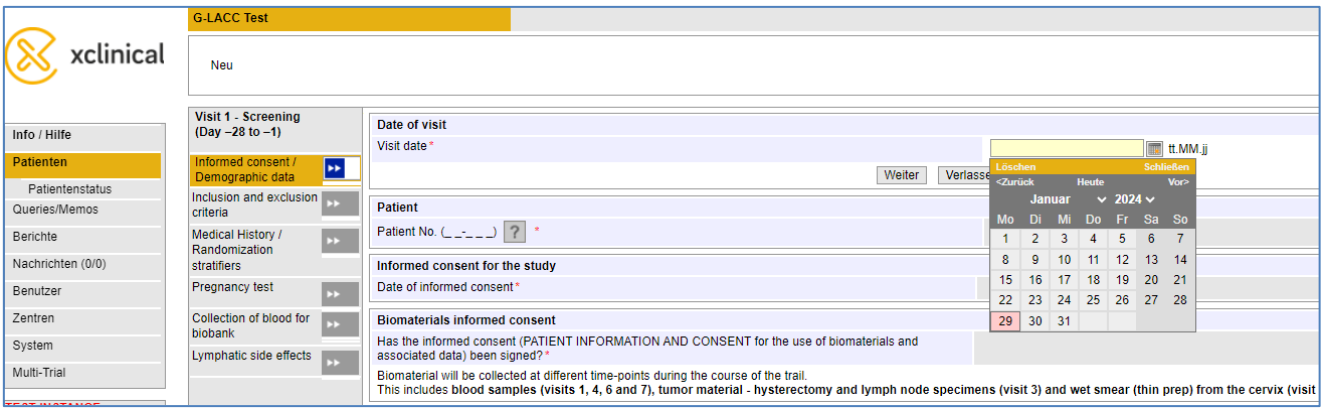

Figure 5: First form of patient

Once date of visit is set, the patient number will be set automatically. It consists of the site number followed by the consecutive number of patient enrolled at the site e. g. 01-002 is the second enrolled patient at site 01.

4. Go to an existing subject

All patients who have already been created in the eCRF can be seen if you click on '*Patients*' in the menu. If there are more than 25 patients, the list is initially displayed page by page. You can then use the page selection above the patient list to go to the next page or use [Show all] to display the complete list.

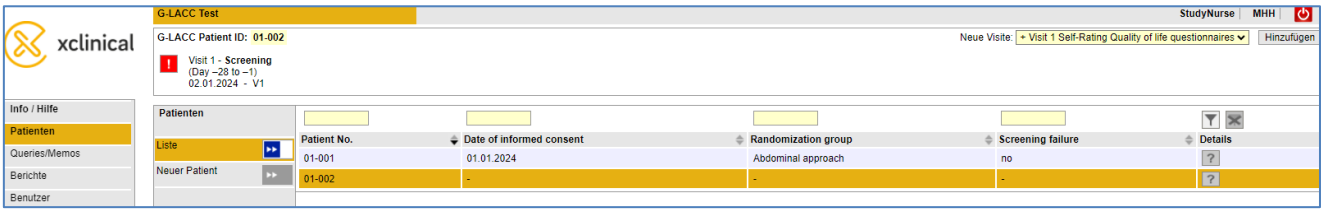

Figure 6: Patients – Overview

A patient is selected for editing by clicking on the patient number in the patient list.

5. The visit plan

All visits created for the patient as well as **visit-independent** forms are listed in chronological order at the top of the screen. The date that is displayed next to the event is the visit date.

The next visits as well as **visit-independent forms** (e.g. Post-operative complications, Serious Adverse Events (SAEs) can be added to the eCRF by selecting from a drop-down list in the top right corner.

To enter data for a visit, click on the respective visit name in the list and you will be shown all the forms available for the respective visit.

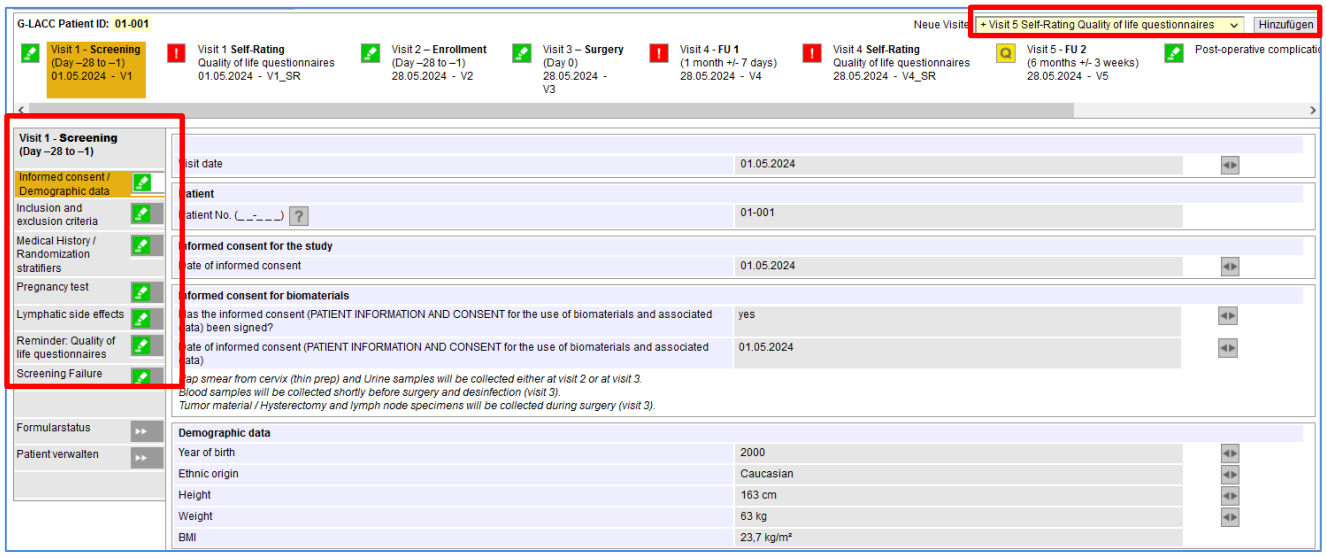

Figure 7: Form and visits selection

Alternatively, you can also use the form status to go to a specific visit or a specific form. To open the form status, click on *'Form status'*.

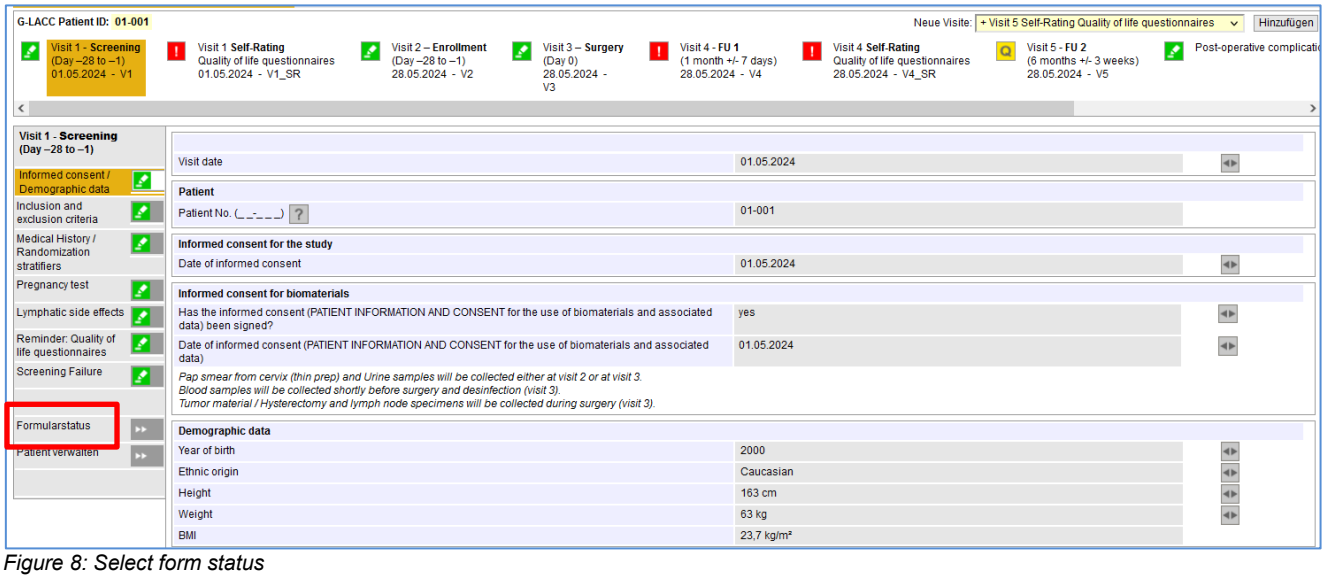

Figure 8: Select form status

From this overview, you can reach each form by simply clicking on the icons of the form. You can also click on ,*Create event*' at the top of the header to create further visits for each patient.

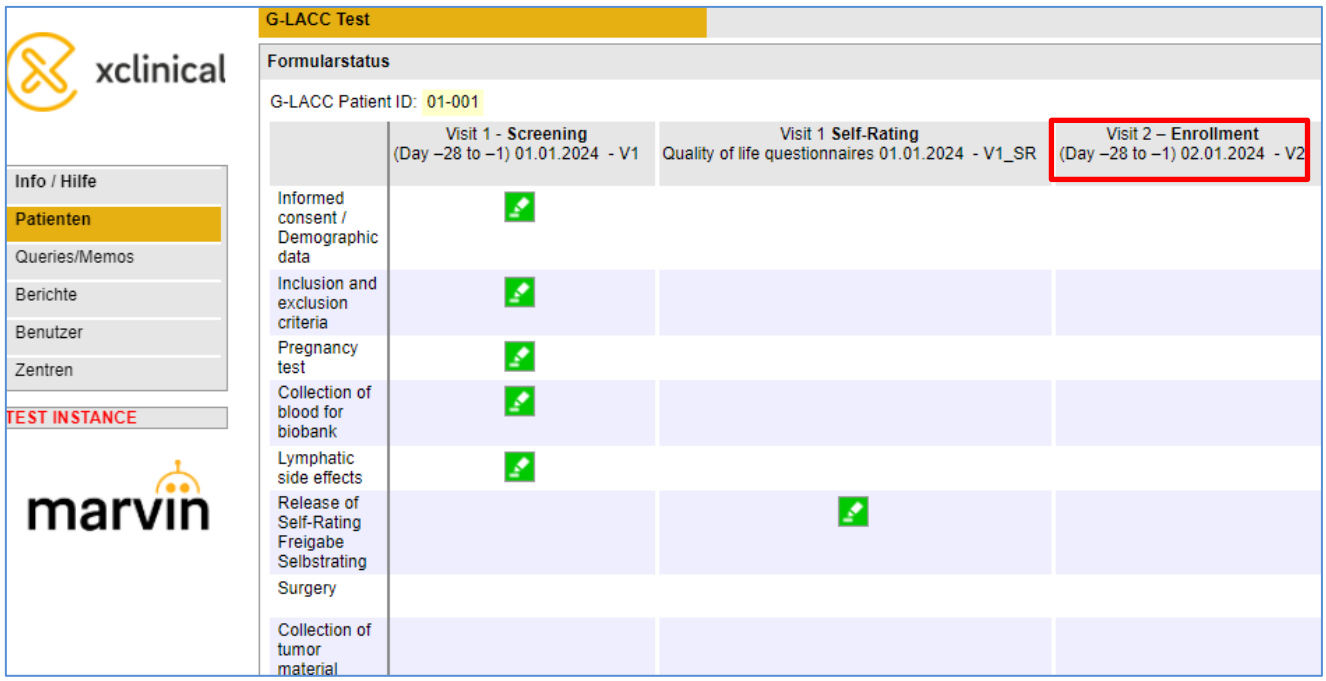

Figure 9: Form status view

6. Form status

	Data entry in this form for this patient has not been done yet.
!	There is mandatory data left to be filled in.
	All mandatory data has been filled in, visit/form is ready to be signed by the monitor.
✓	Data is completely entered and signed by the monitor. Needs to be unlocked by monitor/data manager if data needs to be changed.
Q	There is an open query. (see chapter 9)
Q	Query has been answered (not closed yet).

7. Data entry workflow

Fields that are available for data entry available, are highlighted in yellow.

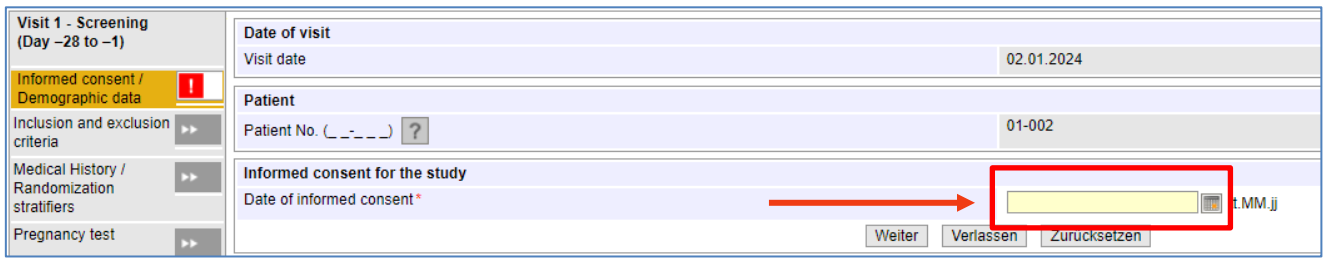

Figure 10: Input fields

The entered data will be saved by clicking on '*Next*'.

Do not forget to click *'Next'* before you leave a form.

Mandatory fields are marked with a red asterisk (*). If not all mandatory fields have been filled in when you save the form, you will receive the following message "Please complete the input fields marked with *." The data is stored in spite of this message and you can continue the data entry on a different form or a different patient. The form will be marked with a red exclamation mark ! to remind you that there is still data missing.
Dates can either be entered directly in the corresponding field or selected from a calendar. To display the calendar, click on the small calendar symbol next to the input field.

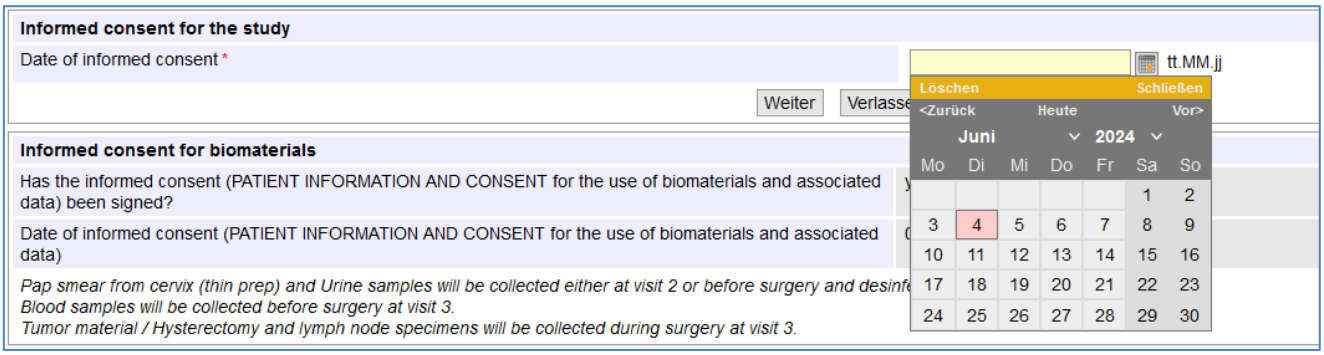

Figure 11: Dates with calendar

Data entry in items with **radio buttons** is made through clicking the respective option. Multiple choices are <u>not</u> possible.

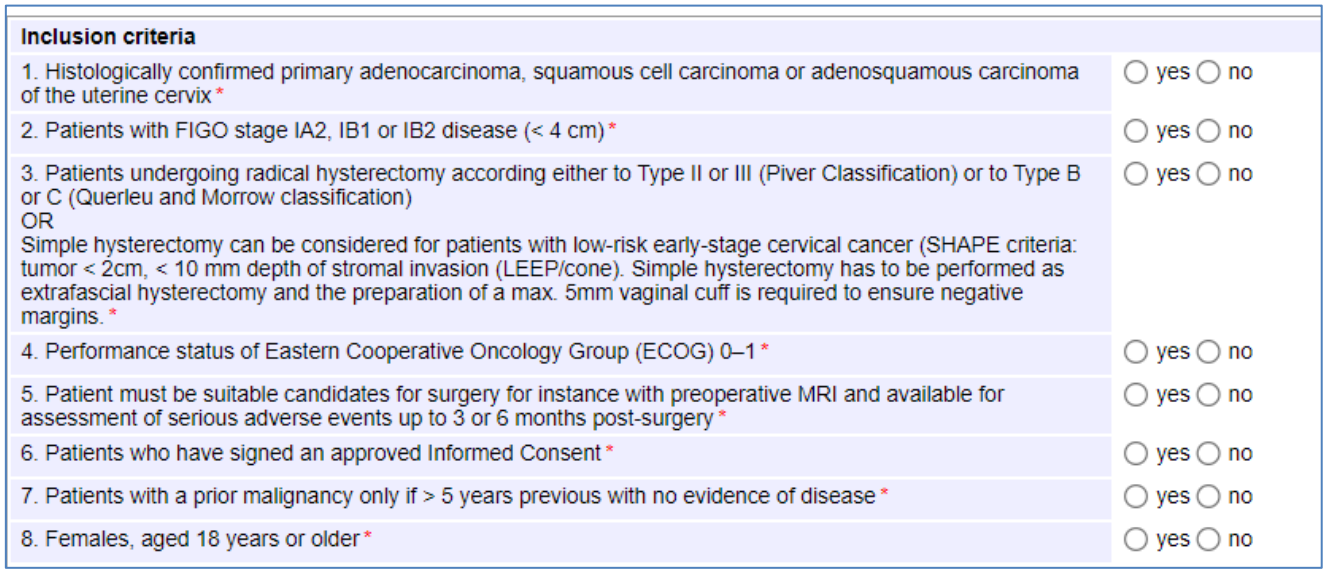

Figure 12: Radio buttons

If you want to enter or change data in fields that are closed, click on the double arrow  to the right of the respective field.

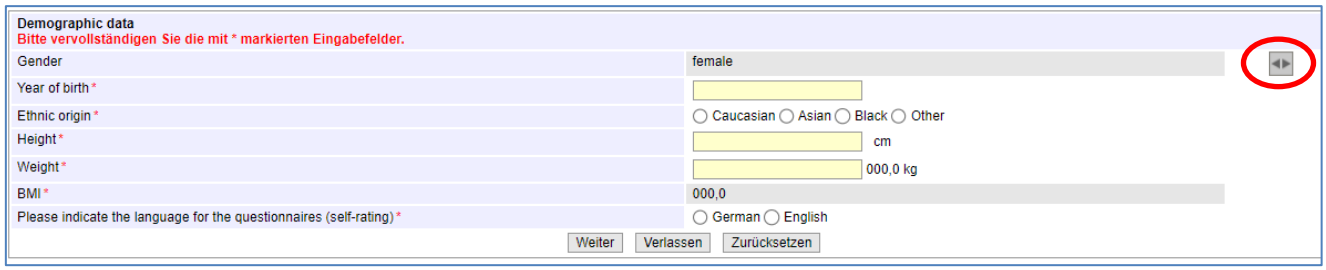

Figure 13: Data change

To change data, click on the double arrow icon, then enter a new value or select '*Reset*' to restore the original empty state and enter a reason for the change. To complete the change, click on '*OK*'.

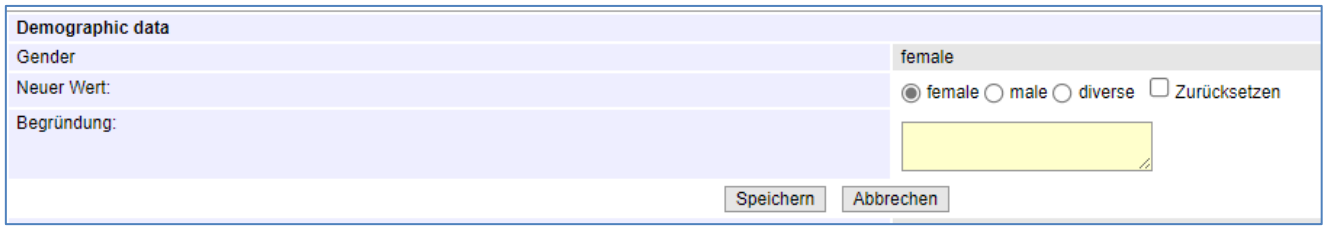

Figure 14: Data change with reason

To change the data in the horizontal view, click on the single arrow icon  , then the fields appear separately, each with a double arrow icon.

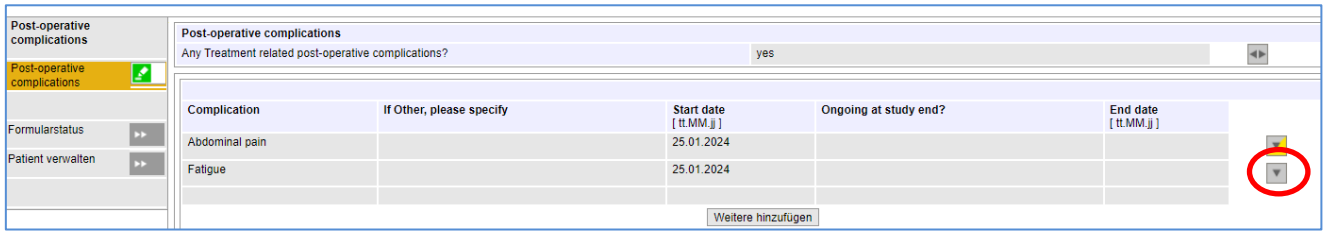

Figure 15: Data change with horizontal display

Additional help or notes are displayed when you click the question mark 

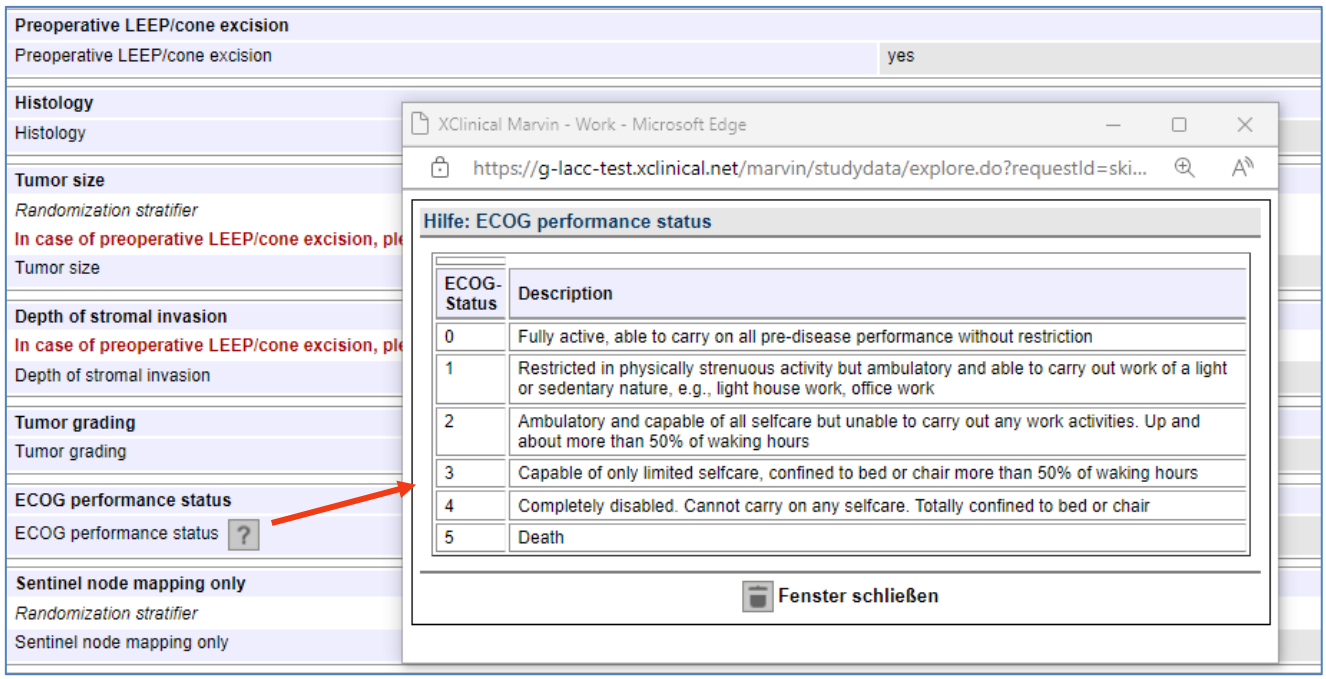

Figure 16: Help / Notes

8. Patient account management

To create a patient account, select a patient, go to *'Patient Mgmt.'* and click *'Create account'*.

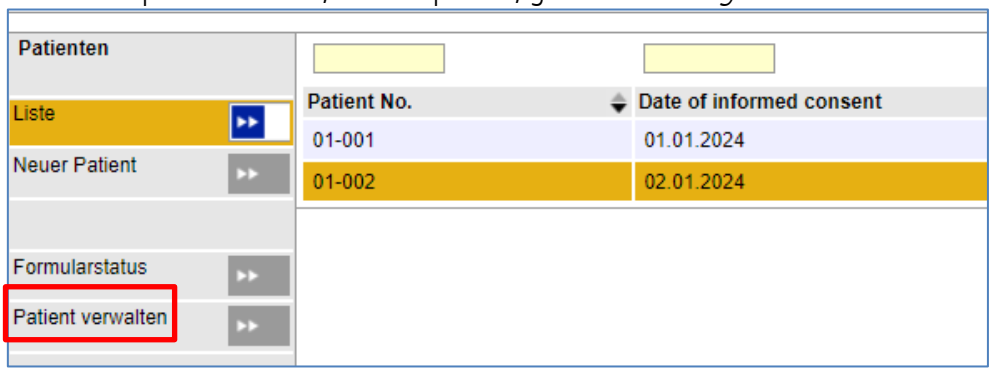

Figure 17: Patient Mgmt.

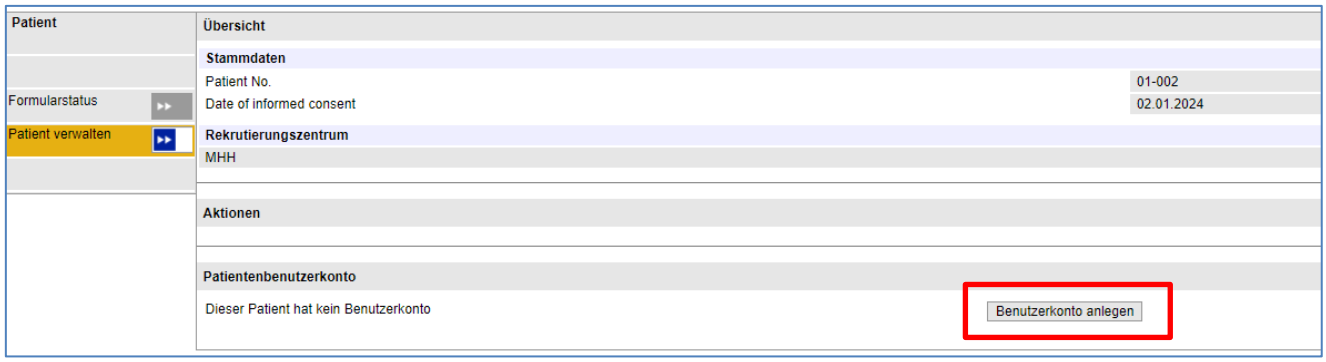

Figure 18: Create Patient Account

The patient account is created and activated. The user name corresponds to the patient ID.

- The access data can be provided to the patient via email. If you click 'Send', enter a patient email address and click 'Save and Send', the username and password will be sent to the patient.

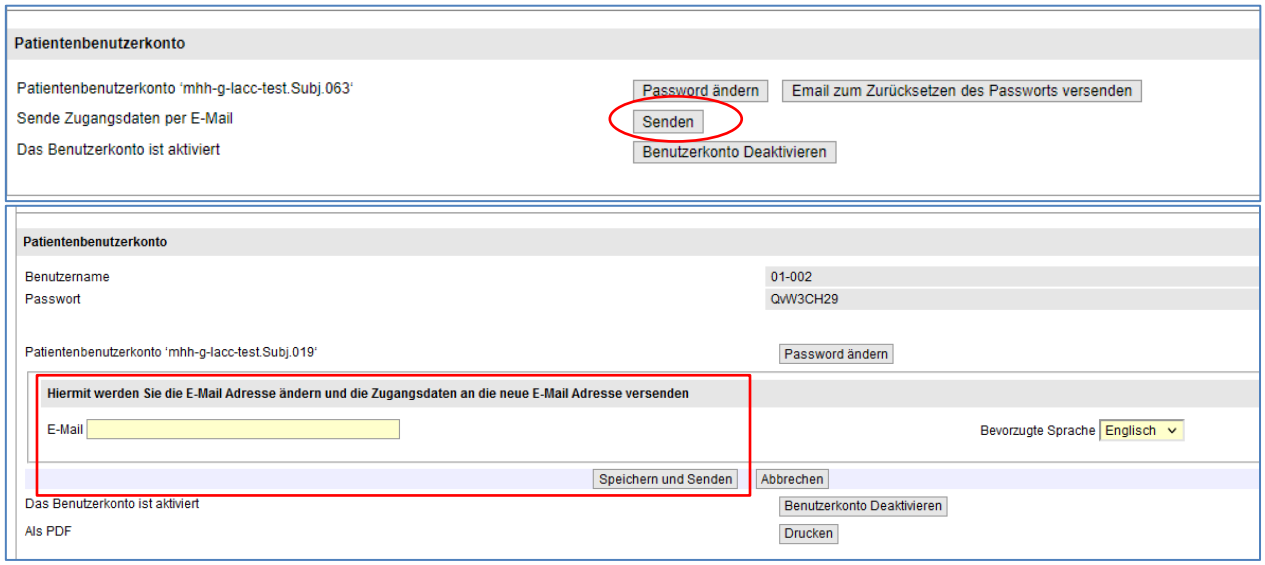

Figure 19: Patient Management / access data via email

OR

Please use either one method (access data via email) or another (access data as printed .pdf file) as different passwords are created by the system

- The access data can be provided to the patient as a printed .pdf file. When you click '*Print*', the .pdf file will be created.

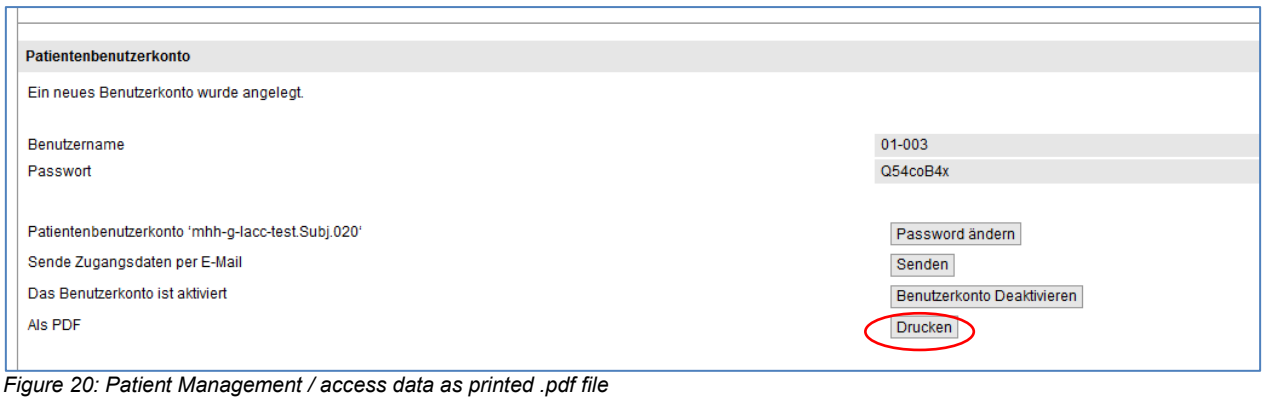

Figure 20: Patient Management / access data as printed .pdf file

To deactivate a patient account after completing documentation, click *'Disable account'.*

The 'Print' option is only available as long as the patient has not yet changed the specified password.

9. Enrollment / Randomization

Randomization will only be performed after verification of the patient's eligibility and signed written informed consent. All inclusion criteria and no exclusion criteria must be met. Furthermore, baseline (Visit 1 Self-Rating) assessment of quality of life questionnaires will be performed prior to randomization

Requirement for Enrollment:

- **Entry of the inclusion/exclusion criteria and confirmation of participation in the study (Screening)**
- **Entry of baseline (Visit 1 Self-Rating) assessment of quality of life questionnaires**
- **Entry of Randomization stratifier (Screening)**

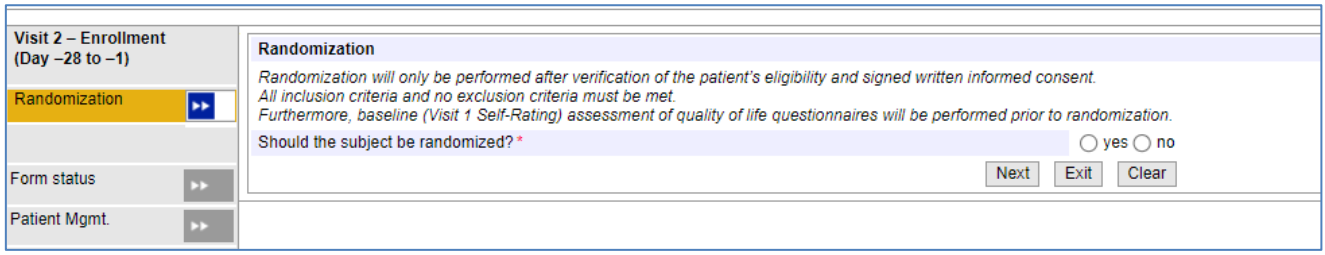

Figure 21: Enrollment / Randomization form

Randomization is triggered by entering "yes" to the question "Should the subject be randomized?".

10. Warnings

The system message will be displayed, if the field format is wrong.

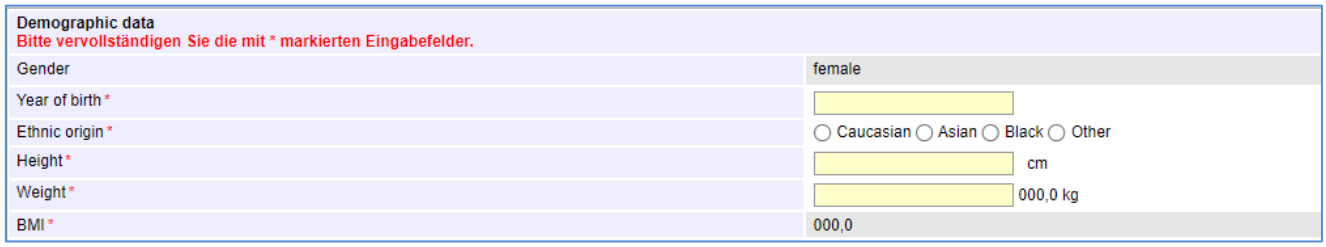

Figure 22: Form with warning

11. Queries

Queries indicate inconsistencies in the entered data. Queries are marked with the following symbol: Q. Automatic queries appear immediately after the form has been saved.

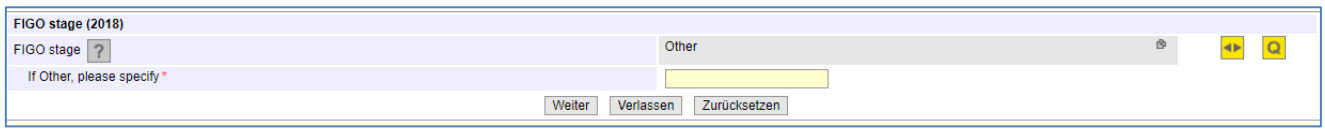

Figure 23: Form with query

Open queries are indicated by a .Please read the text of the query carefully and answer the query either with a correction of the data (if applicable) or an explanation of why the data entered is correct. To answer a query, click on (if you click on , only the text of the query is displayed).

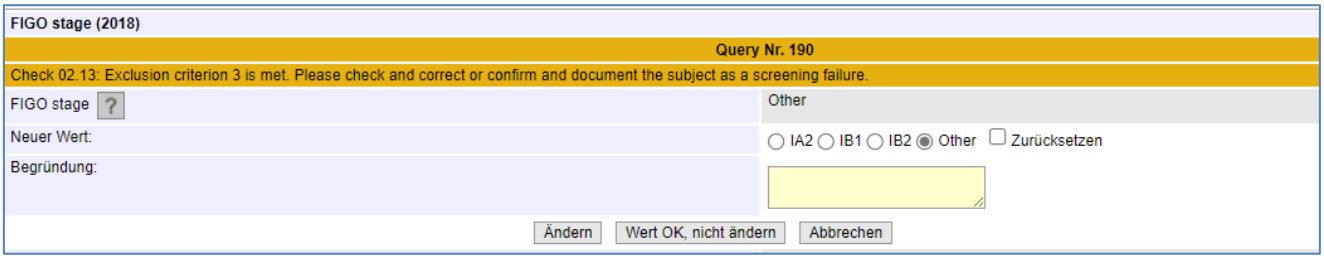

Figure 24: Query - edit mode

To confirm the original value, please enter a reason in the field *Reason* and click ‚Value OK*, no.* If you want to correct the entered value, enter the changed value in the *New value* field, enter a reason for the change in the *Reason* field and click on '*Change*'. To *reset* the field to its original empty state, select '*Reset*', enter a reason and click on '*Change*'.

After answering the query, the symbol changes to . This symbol indicates that the query has been answered but has not yet been closed by the monitor or data manager.

12. Signatures

After the data have been completely entered, an investigator confirms with the electronic signature that the data is accurate. To sign the form or the visit, click on '*Sign form* ' or '*Sign event* ' at the end of the respective page. You will be asked to enter your username and password. The signed and locked form (visit) is marked with a .

When the documentation of a patient in the eCRF has been completed, i.e. all necessary forms have been entered, all queries answered and all forms signed, the data verification form must be added and signed by the principal investigator or his representative. The principal investigator (or representative) is able to sign all data for subject with a single signature. To sign all data for subject, select the subject in the patient list and click on '*Patient Mgmt.*' (Patient Management). The patient management form will open. Click on '*Sign patient data'*, enter your user name and password and click again on '*Sign patient data'*. All forms for the subject will be marked with .

13. General data entry conventions

Missing data

For some fields it is possible to mark missing data by entering a code. This applies to numeric fields or dates. The following codes are available:

- ND = not done
- UNK = unknown

- NA = not applicable

Example:
Only the month and year of the start of an adverse event are known. For the day, '*NA*' is entered.

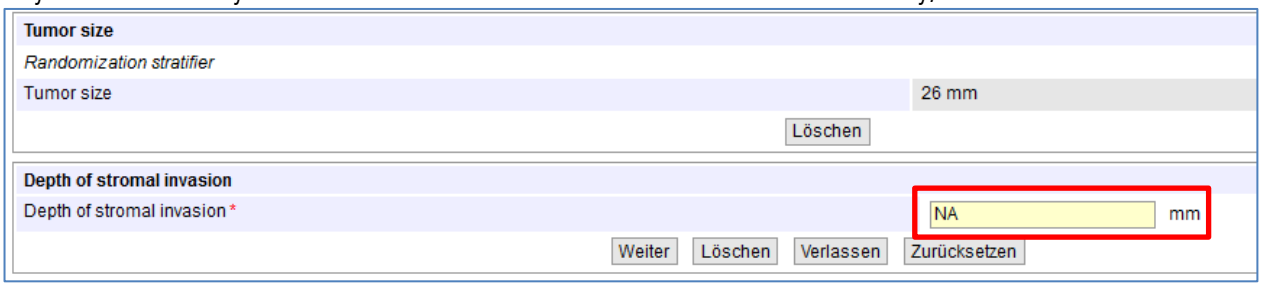

Figure 25 "NA" as missing data

Show / hide fields or forms

Some fields or forms are only shown depending on the entries in other fields. These fields are only displayed after clicking on '*Next*'.

Example:
Questions that are initially answered with 'Yes / No', but require a more detailed description.

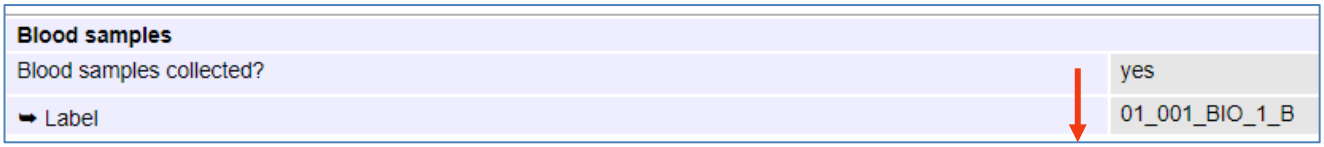

Figure 26: "Next" to show fields

Only if blood samples collected, further fields for the exact documentation appear.

14. Form specific data entry conventions

14.1. Inclusion / Exclusion criteria

If a subject is a screening failure, please enter the data for the screening visit. In the form Visit 1 – Screening / Screening Failure answer the question "Is the subject a screening failure?" with "Yes" and enter the reason, e.g. which inclusion criterion is not met. No further entries in the eCRF are necessary for screening failures. Please do not forget to sign the forms.

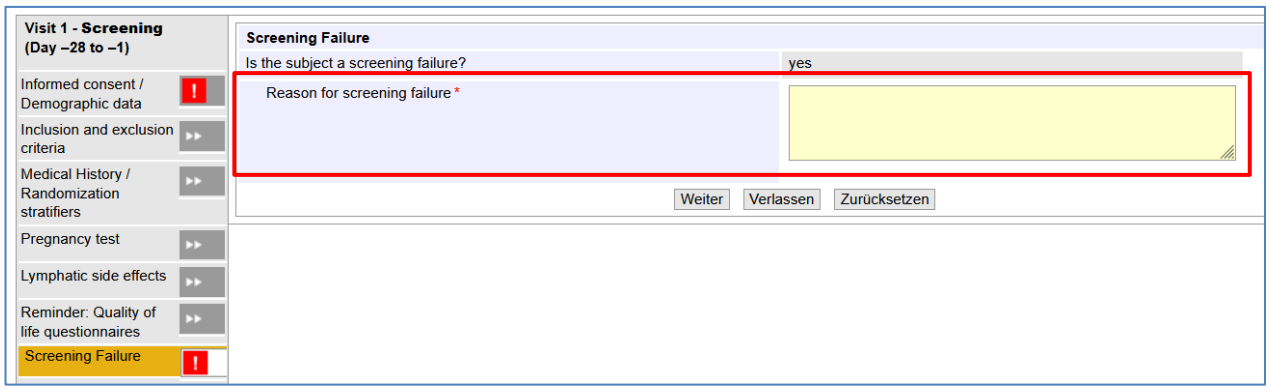

Figure 27: eCRF entries for screening failure

14.2. Pregnancy

At screening you will be asked for female subjects only "Is the patient of childbearing potential?. In case of no childbearing potential two yes/no fields will be enabled for the specification. In all other visits the "Pregnancy test" form will be disabled.
In case of childbearing potential enter the answer to the question "Pregnancy test performed?" and click *"Next".*
If a "Pregnancy test" has been performed, date and result have to be entered into the two enabled fields.

14.3. Activation of forms for patients (self-rating)

The self-rating forms will be activated by the site at the scheduled times. The data entry of the self-ratings by the patient can only take place after activation.
After the patient has entered the self-ratings, the investigator or study nurse must sign the visit to prevent the patient from subsequently changing the entries.

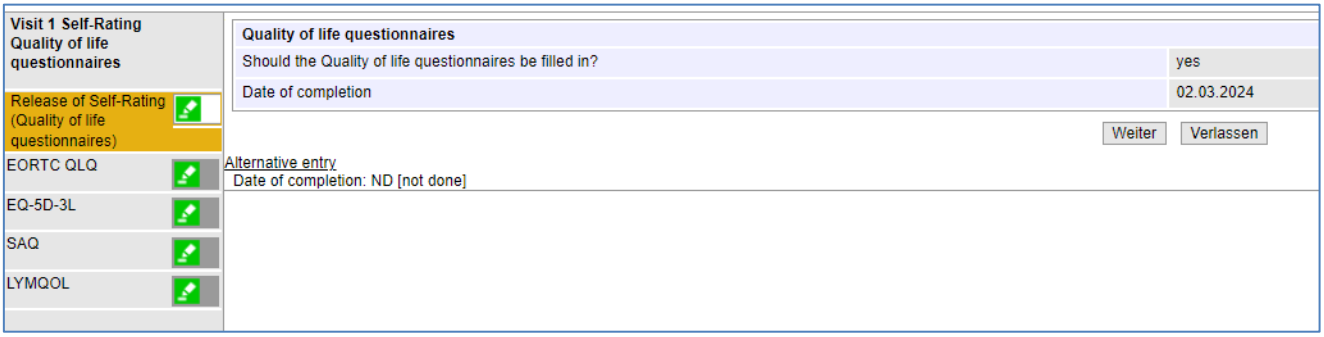

Figure 28: Activation of forms for patients (self-rating)

14.4. Post-operative complications

Please record post-operative complication and state if any of the following adverse events occurred: abdominal pain, constipation, fatigue, paresthesia, peripheral sensory neuropathy, urinary incontinence, urinary retention, dyspareunia, pelvic pain, lymphedema, hot flashes.

Treatment related post-operative complications will be recorded starting directly after surgery up to one year thereafter with a first assessment 30 days post-surgery (visits 4 to 6).

Please document each post-operative complication in a separate line of the sections "Post-operative complications" of the form "Post-operative complications". To create additional lines, please click *'Next'* and click *'Add ItemGroup'*.

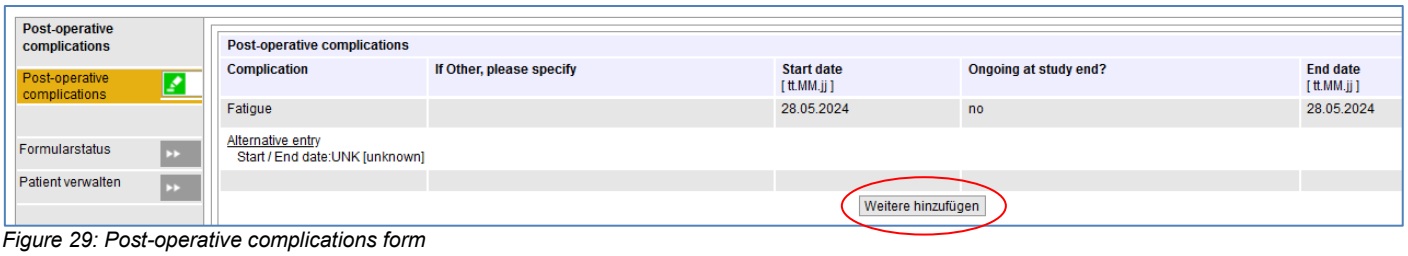

Figure 29: Post-operative complications form

14.5. Serious Adverse Events

Other particularly not treatment related serious adverse events (SAEs) will be captured **from the day of surgery until one year post surgery (visits 3 to 6)**.

Each serious adverse event has to be documented in a separate "SAE" form.
To add another serious adverse event, click on the next form *"SAE: - - -.-.-"* and then on *'Add Form'*.

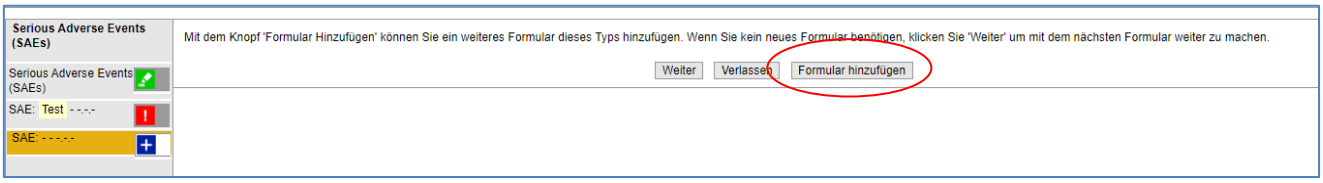

Figure 30: Serious Adverse Events form

14.6. Disease recurrence

In addition to the follow-up visits as scheduled in the study calendar, patients will receive follow-up care according to national guidelines. Follow-up care includes physical examination and medical consultation among other optional procedures (e.g. tumor marker or cytology). In case of abnormal findings during follow-up or clinical suspicion of disease recurrence, imaging diagnostic should be performed. Recurrence of disease must be verified by histopathological assessment. The date of biopsy counts as the date of recurrence. State where the recurrence occurred:

- Type of analysis (CT, MRT, Biopsy, other)
- pelvic recurrences (vaginal vault, parametrium, pelvic lymph nodes, or other)
- extra pelvic recurrences (abdomen, para-aortic lymph nodes, supraclavicular lymph nodes, or other)
- if possible, an additional blood sample should be collected

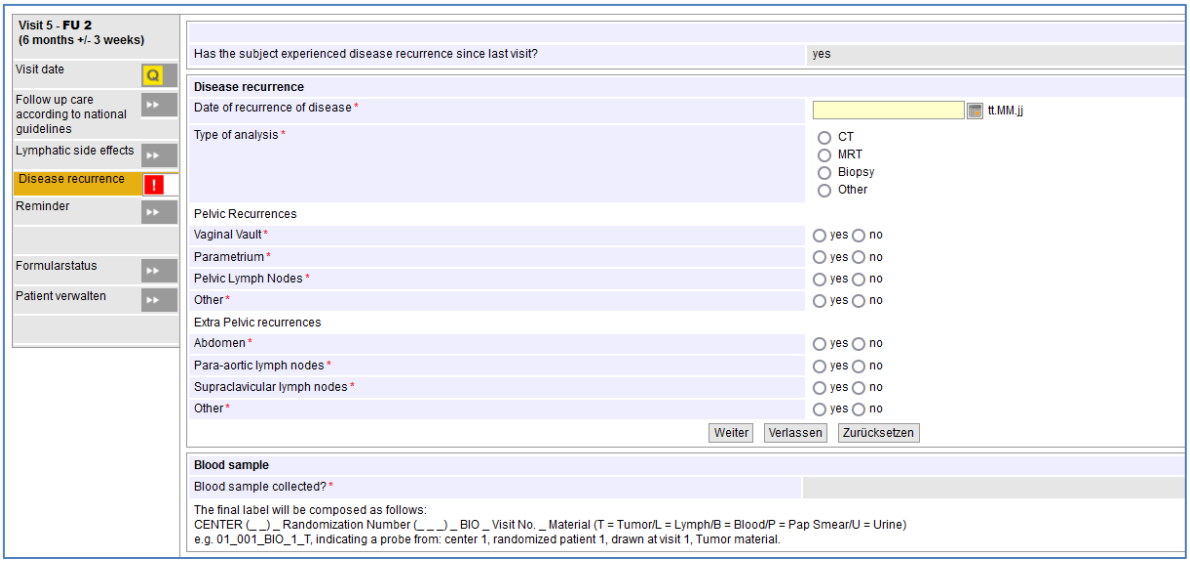

Figure 31: Disease recurrence form

14.7. Protocol deviations

Investigators and/or study nurses at the study site have to document all protocol deviations in the eCRF. The form for documentation of protocol deviations can be accessed in the eCRF on site level. Click on 'Centers' in the left hand side menu bar, click on the center name 'MHH', and click on 'Edit'

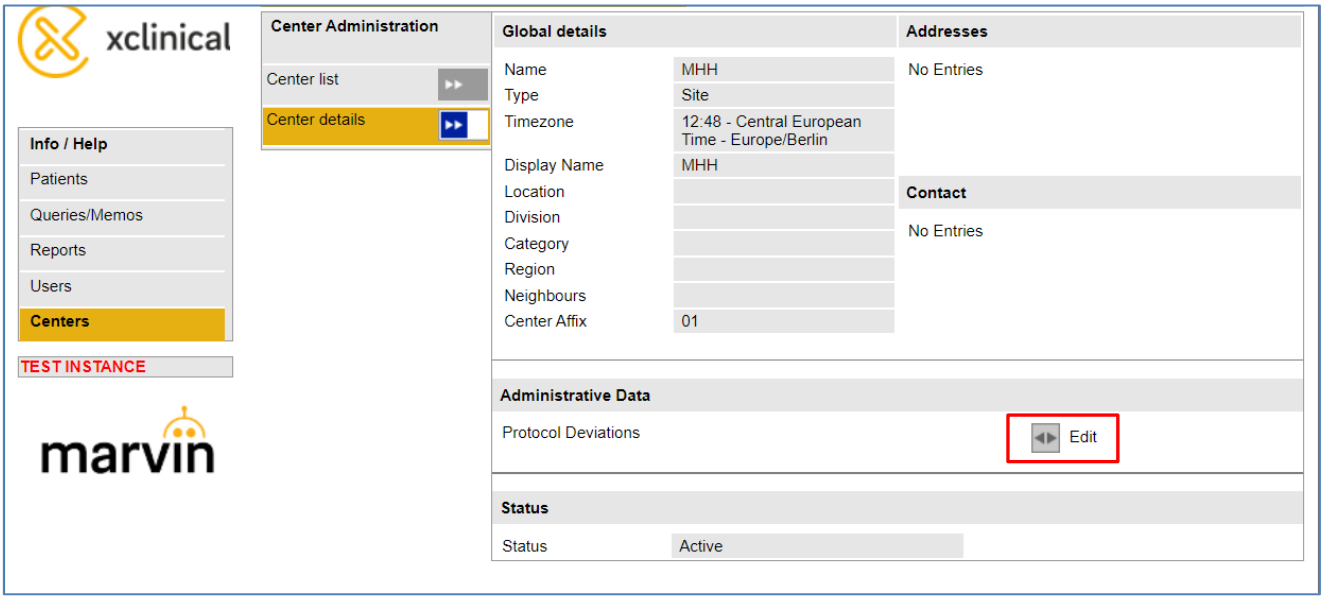

Figure 32: Navigate to forms for protocol deviations

For every protocol deviation a separate form has to be completed with the details of the deviation and measures taken by the study site. The identification number PD ID will be set automatically. It is not always necessarily in consecutive order.

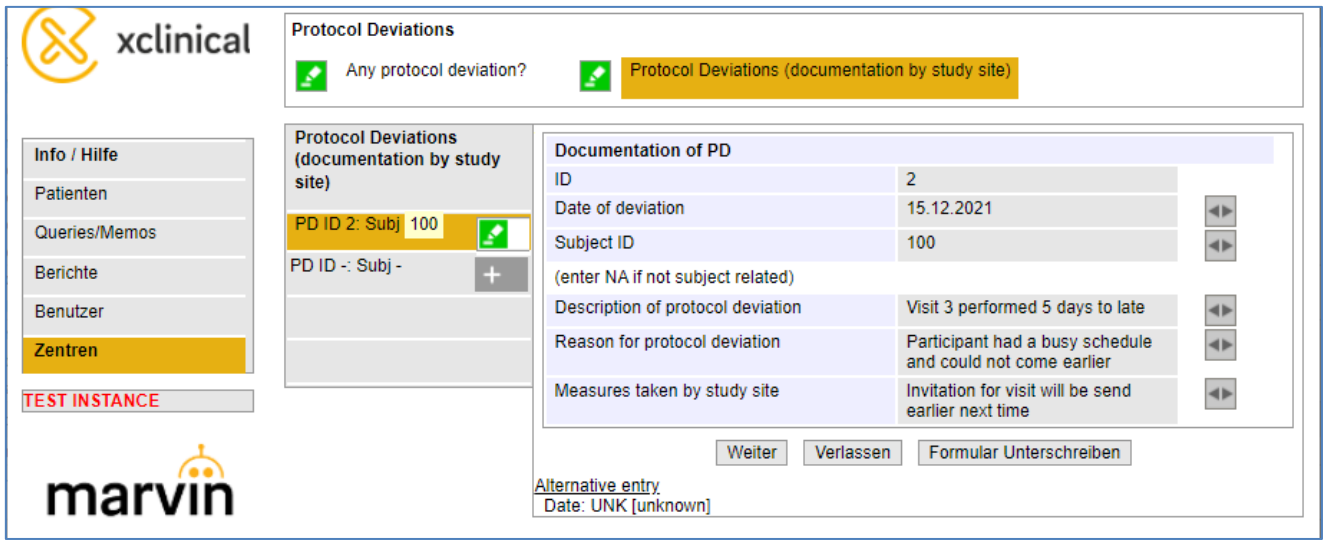

Figure 33: Form for Protocol Deviations

More forms for further protocol deviation can be added by clicking on the last entry in the list of forms without PD ID.

There are separate forms for the documentation of protocol deviations and the assessment of all protocol deviations by the sponsor. These forms are only accessible for users with the role PD Assessment.

14.8. End of study

First enter the „ Date of study end" to the patient and then enter the yes/no field „Study completed according to study protocol?".

In case of study discontinuation the field „reason study participation was discontinued" is enabled after a click on *'Next'*. If "Other reasons" is chosen as reason, you'll be prompted to give the specification for "Other reason". Otherwise if the entry is „Death", you'll be prompted to enter the "Date of death".

15. Contact information

ZKS Data Manager: g-lacc.zks@mh-hannover.de