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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.

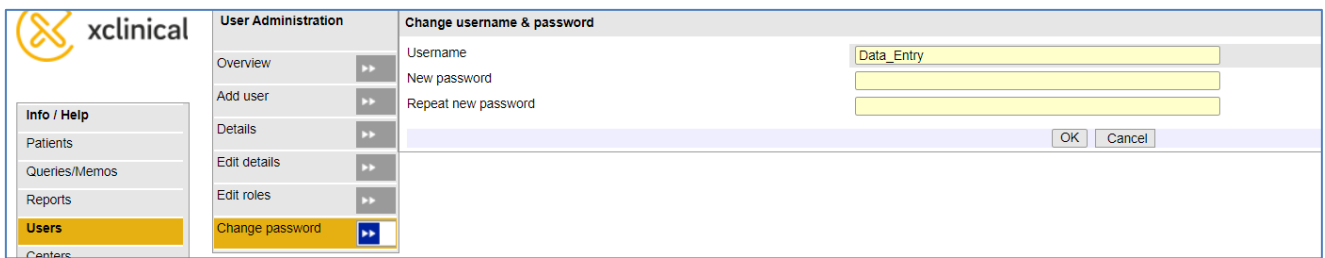


Figure 1: Enter username and password

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.

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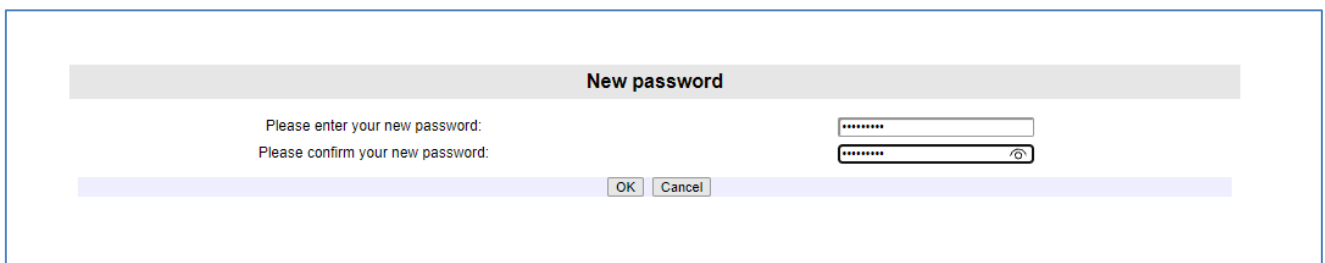


The screenshot shows the xclinical User Administration interface. The 'Change username & password' form is active, with the following fields: Username (Data_Entry), New password, and Repeat new password. The 'Change password' button is highlighted in blue. The interface includes a navigation menu on the left with options like 'Overview', 'Add user', 'Details', 'Edit details', 'Edit roles', and 'Change password'.

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.

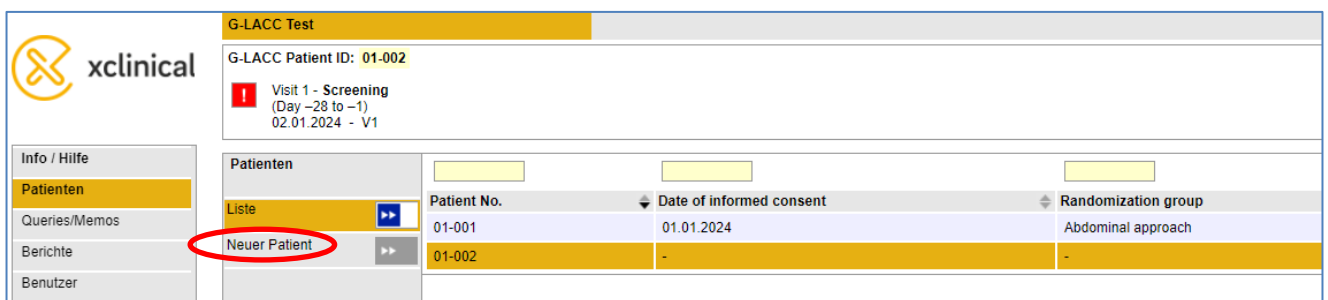


The screenshot shows a 'New password' dialog box. It contains two input fields for 'Please enter your new password:' and 'Please confirm your new password:'. Both fields are masked with asterisks. The dialog box has 'OK' and 'Cancel' buttons at the bottom.

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.



The screenshot shows the xclinical interface for the 'G-LACC Test' study. The 'Patients' section is active, displaying a list of patients. The 'Neuer Patient' button is highlighted with a red circle. The patient list includes columns for 'Patient No.', 'Date of informed consent', and 'Randomization group'. The first patient listed is 01-001, and the second is 01-002.

Patient No.	Date of informed consent	Randomization group
01-001	01.01.2024	Abdominal approach
01-002	-	-

Figure 4: Add new patient

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

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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.

Patient No.	Date of informed consent	Randomization group	Screening failure	Details
01-001	01.01.2024	Abdominal approach	no	?
01-002	-	-	-	?

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.

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G-LACC Patient ID: 01-001

Neue Visite: + Visit 5 Self-Rating Quality of life questionnaires Hinzufügen

Visit 1 - Screening (Day -28 to -1) 01.05.2024 - V1
 Visit 1 Self-Rating Quality of life questionnaires 01.05.2024 - V1_SR
 Visit 2 - Enrollment (Day -28 to -1) 28.05.2024 - V2
 Visit 3 - Surgery (Day 0) 28.05.2024 - V3
 Visit 4 - FU 1 (1 month +/- 7 days) 28.05.2024 - V4
 Visit 4 Self-Rating Quality of life questionnaires 28.05.2024 - V4_SR
 Visit 5 - FU 2 (6 months +/- 3 weeks) 28.05.2024 - V5
 Post-operative complications

Visit 1 - Screening (Day -28 to -1)

Informed consent / Demographic data
 Inclusion and exclusion criteria
 Medical History / Randomization stratifiers
 Pregnancy test
 Lymphatic side effects
 Reminder: Quality of life questionnaires
 Screening Failure

Formularstatus
 Patient verwalten

Visit date: 01.05.2024

Patient: Patient No. (_ - _ -) ? 01-001

Informed consent for the study: Date of informed consent: 01.05.2024

Informed consent for biomaterials: Has the informed consent (PATIENT INFORMATION AND CONSENT for the use of biomaterials and associated data) been signed? yes

Date of informed consent (PATIENT INFORMATION AND CONSENT for the use of biomaterials and associated data): 01.05.2024

Pap smear from cervix (thin prep) and Urine samples will be collected either at visit 2 or at visit 3. Blood samples will be collected shortly before surgery and desinfection (visit 3). Tumor material / Hysterectomy and lymph node specimens will be collected during surgery (visit 3).

Demographic data: Year of birth: 2000, Ethnic origin: Caucasian, Height: 163 cm, Weight: 63 kg, BMI: 23.7 kg/m²

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'.

G-LACC Patient ID: 01-001

Neue Visite: + Visit 5 Self-Rating Quality of life questionnaires Hinzufügen

Visit 1 - Screening (Day -28 to -1) 01.05.2024 - V1
 Visit 1 Self-Rating Quality of life questionnaires 01.05.2024 - V1_SR
 Visit 2 - Enrollment (Day -28 to -1) 28.05.2024 - V2
 Visit 3 - Surgery (Day 0) 28.05.2024 - V3
 Visit 4 - FU 1 (1 month +/- 7 days) 28.05.2024 - V4
 Visit 4 Self-Rating Quality of life questionnaires 28.05.2024 - V4_SR
 Visit 5 - FU 2 (6 months +/- 3 weeks) 28.05.2024 - V5
 Post-operative complications

Visit 1 - Screening (Day -28 to -1)

Informed consent / Demographic data
 Inclusion and exclusion criteria
 Medical History / Randomization stratifiers
 Pregnancy test
 Lymphatic side effects
 Reminder: Quality of life questionnaires
 Screening Failure

Formularstatus
 Patient verwalten

Visit date: 01.05.2024

Patient: Patient No. (_ - _ -) ? 01-001

Informed consent for the study: Date of informed consent: 01.05.2024

Informed consent for biomaterials: Has the informed consent (PATIENT INFORMATION AND CONSENT for the use of biomaterials and associated data) been signed? yes

Date of informed consent (PATIENT INFORMATION AND CONSENT for the use of biomaterials and associated data): 01.05.2024

Pap smear from cervix (thin prep) and Urine samples will be collected either at visit 2 or at visit 3. Blood samples will be collected shortly before surgery and desinfection (visit 3). Tumor material / Hysterectomy and lymph node specimens will be collected during surgery (visit 3).

Demographic data: Year of birth: 2000, Ethnic origin: Caucasian, Height: 163 cm, Weight: 63 kg, BMI: 23.7 kg/m²

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.

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	Visit 1 - Screening (Day -28 to -1) 01.01.2024 - V1	Visit 1 Self-Rating Quality of life questionnaires 01.01.2024 - V1_SR	Visit 2 - Enrollment (Day -28 to -1) 02.01.2024 - V2
Informed consent / Demographic data	✓		
Inclusion and exclusion criteria	✓		
Pregnancy test	✓		
Collection of blood for biobank	✓		
Lymphatic side effects	✓		
Release of Self-Rating Freigabe Selbstrating Surgery		✓	
Collection of tumor material			

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.



There is an open query. (see chapter 9)



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

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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.

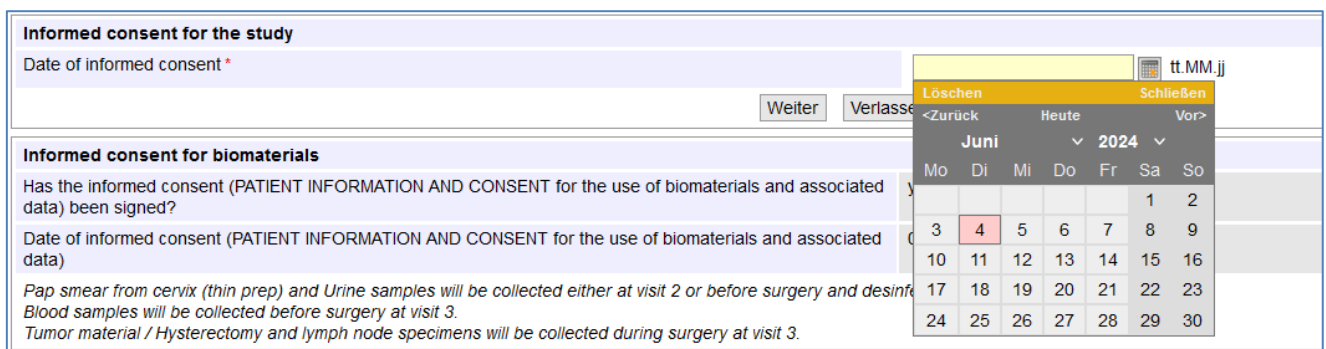
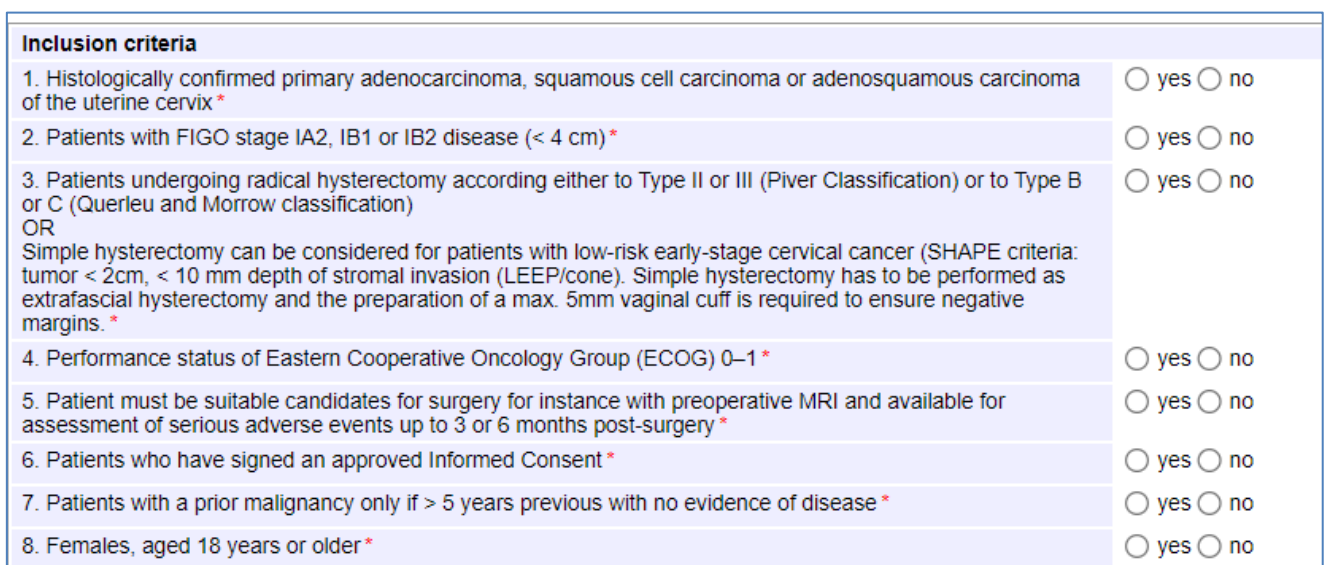


Figure 11: Dates with calendar


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

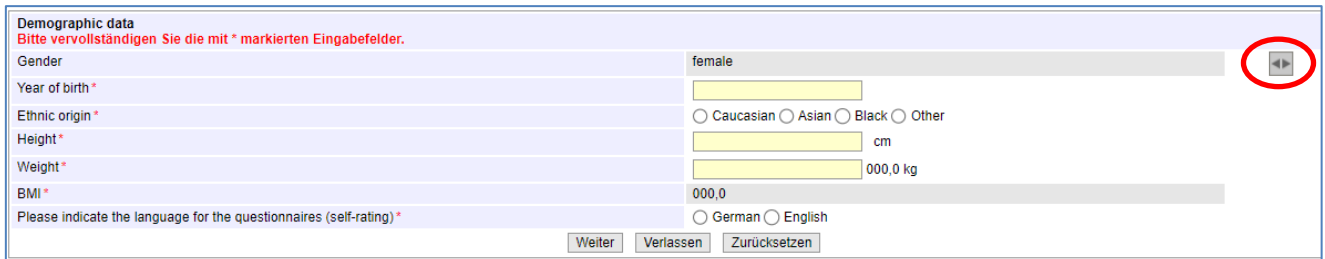


Inclusion criteria	
1. Histologically confirmed primary adenocarcinoma, squamous cell carcinoma or adenosquamous carcinoma of the uterine cervix *	<input type="radio"/> yes <input type="radio"/> no
2. Patients with FIGO stage IA2, IB1 or IB2 disease (< 4 cm) *	<input type="radio"/> yes <input type="radio"/> no
3. Patients undergoing radical hysterectomy according either to Type II or III (Piver Classification) or to Type B or C (Querleu and Morrow classification) OR Simple hysterectomy can be considered for patients with low-risk early-stage cervical cancer (SHAPE criteria: tumor < 2cm, < 10 mm depth of stromal invasion (LEEP/cone). Simple hysterectomy has to be performed as extrafascial hysterectomy and the preparation of a max. 5mm vaginal cuff is required to ensure negative margins. *	<input type="radio"/> yes <input type="radio"/> no
4. Performance status of Eastern Cooperative Oncology Group (ECOG) 0-1 *	<input type="radio"/> yes <input type="radio"/> no
5. Patient must be suitable candidates for surgery for instance with preoperative MRI and available for assessment of serious adverse events up to 3 or 6 months post-surgery *	<input type="radio"/> yes <input type="radio"/> no
6. Patients who have signed an approved Informed Consent *	<input type="radio"/> yes <input type="radio"/> no
7. Patients with a prior malignancy only if > 5 years previous with no evidence of disease *	<input type="radio"/> yes <input type="radio"/> no
8. Females, aged 18 years or older *	<input type="radio"/> yes <input type="radio"/> no


Figure 12: Radio buttons

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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.



Demographic data
Bitte vervollständigen Sie die mit * markierten Eingabefelder.

Gender female 

Year of birth *

Ethnic origin * Caucasian Asian Black Other

Height * cm

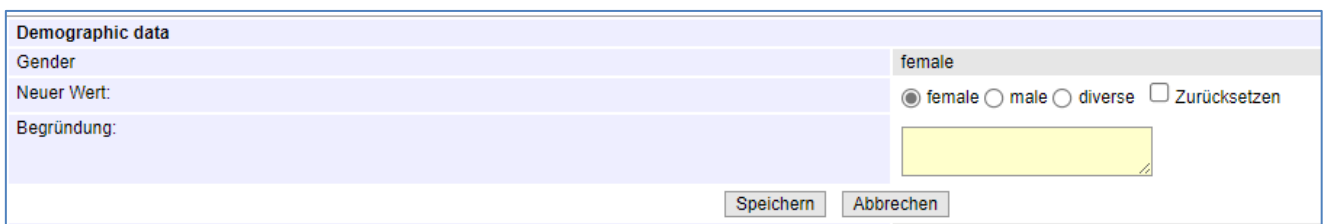
Weight * 000,0 kg

BMI * 000,0

Please indicate the language for the questionnaires (self-rating) * German English

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'.




Demographic data

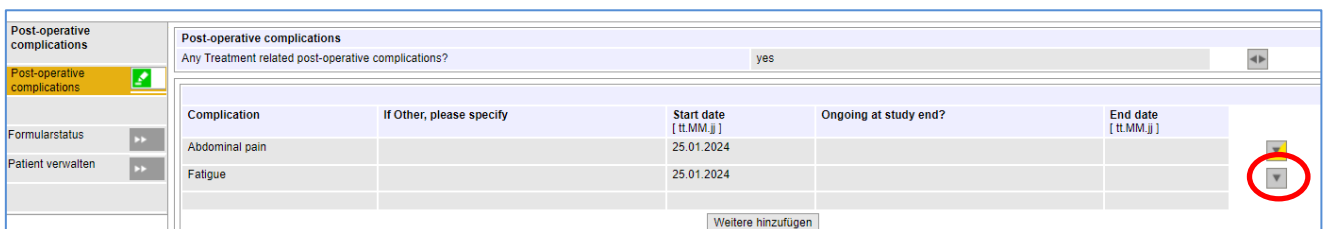
Gender female

Neuer Wert: female male diverse Zurücksetzen


Begründung:

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.



Post-operative complications

Any Treatment related post-operative complications? yes 

Complication	If Other, please specify	Start date [tt.MM.jj]	Ongoing at study end?	End date [tt.MM.jj]
Abdominal pain		25.01.2024		
Fatigue		25.01.2024		





Figure 15: Data change with horizontal display

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

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The screenshot shows a data entry form with a help window open. The help window is titled "Hilfe: ECOG performance status" and contains a table with the following data:

ECOG-Status	Description
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all selfcare but unable to carry out any work activities. Up and about more than 50% of waking hours
3	Capable of only limited selfcare, confined to bed or chair more than 50% of waking hours
4	Completely disabled. Cannot carry on any selfcare. Totally confined to bed or chair
5	Death

An orange arrow points from the "ECOG performance status" field in the form to the help window.

Figure 16: Help / Notes

8. Patient account management

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

The screenshot shows the 'Patient Mgmt.' interface. On the left, there is a sidebar with the following options: 'Liste', 'Neuer Patient', 'Formularstatus', and 'Patient verwalten'. The 'Patient verwalten' option is highlighted with a red box. The main area displays a table with the following data:

Patient No.	Date of informed consent
01-001	01.01.2024
01-002	02.01.2024

Figure 17: Patient Mgmt.

The screenshot shows the 'Create Patient Account' interface. On the left, there is a sidebar with the following options: 'Patient', 'Formularstatus', and 'Patient verwalten'. The 'Patient verwalten' option is highlighted with a blue arrow. The main area displays the following information:

Übersicht

Stammdaten

Patient No. 01-002

Date of informed consent 02.01.2024

Rekrutierungszentrum

MHH

Aktionen

Patientenbenutzerkonto

Dieser Patient hat kein Benutzerkonto

Benutzerkonto anlegen

The 'Benutzerkonto anlegen' button is highlighted with a red box.

Figure 18: Create Patient Account

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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.

The screenshot shows two panels of the patient management interface. The top panel, titled 'Patientenbenutzerkonto', shows an account for 'mhh-g-lacc-test.Subj.063' with buttons for 'Password ändern', 'Email zum Zurücksetzen des Passworts versenden', 'Senden' (circled in red), and 'Benutzerkonto Deaktivieren'. The bottom panel shows an account for 'mhh-g-lacc-test.Subj.019' with fields for 'Benutzername' (01-002) and 'Passwort' (QwW3CH29). It includes a 'Password ändern' button, a red-bordered box containing the text 'Hiermit werden Sie die E-Mail Adresse ändern und die Zugangsdaten an die neue E-Mail Adresse versenden' and an 'E-Mail' input field, a 'Speichern und Senden' button, and a 'Bevorzugte Sprache' dropdown set to 'Englisch'. Other buttons include 'Abbrechen', 'Benutzerkonto Deaktivieren', and 'Drucken'.

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.

The screenshot shows the 'Patientenbenutzerkonto' interface for a newly created account. It displays the message 'Ein neues Benutzerkonto wurde angelegt.' and shows the account details for 'mhh-g-lacc-test.Subj.020' with 'Benutzername' 01-003 and 'Passwort' Q54coB4x. Buttons for 'Password ändern', 'Senden', 'Benutzerkonto Deaktivieren', and 'Drucken' (circled in red) are visible. The 'Als PDF' option is also present.

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.

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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: . Automatic queries appear immediately after the form has been saved.

Figure 23: Form with query

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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).

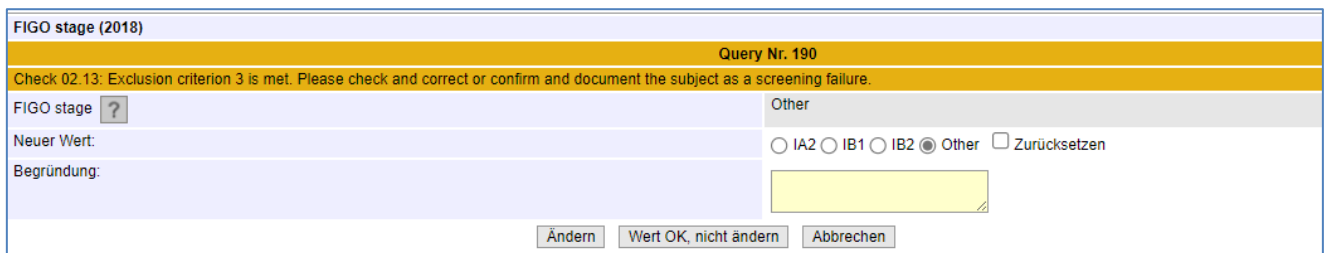





Figure 24: Query - edit mode

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

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- NA = not applicable

Example:

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

Tumor size	
Randomization stratifier	
Tumor size	26 mm
<input type="button" value="Löschen"/>	
Depth of stromal invasion	
Depth of stromal invasion *	NA mm
<input type="button" value="Weiter"/> <input type="button" value="Löschen"/> <input type="button" value="Verlassen"/> <input type="button" value="Zurücksetzen"/>	

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.

Blood samples	
Blood samples collected?	yes
Label	01_001_BIO_1_B

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.

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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).

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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'.

Complication	If Other, please specify	Start date [tt.MM.jj]	Ongoing at study end?	End date [tt.MM.jj]
Fatigue		28.05.2024	no	28.05.2024
Alternative entry Start / End date:UNK [unknown]				

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

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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.

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The screenshot shows the 'xclinical' interface for 'Protocol Deviations'. It features a sidebar on the left with navigation links: 'Info / Hilfe', 'Patienten', 'Queries/Memos', 'Berichte', 'Benutzer', and 'Zentren'. Below the sidebar is a 'TEST INSTANCE' label and the 'marvin' logo. The main content area is titled 'Protocol Deviations' and contains several sections:

- Protocol Deviations (documentation by study site):** A list of entries, including 'PD ID 2: Subj 100' with a green checkmark icon and a '+' icon for adding new entries.
- Documentation of PD:** A table with the following fields:

ID	2	
Date of deviation	15.12.2021	◀ ▶
Subject ID	100	◀ ▶
(enter NA if not subject related)		
Description of protocol deviation	Visit 3 performed 5 days to late	◀ ▶
Reason for protocol deviation	Participant had a busy schedule and could not come earlier	◀ ▶
Measures taken by study site	Invitation for visit will be send earlier next time	◀ ▶
- Alternative entry:** A section with a 'Date' field containing 'UNK [unknown]'. Below this are buttons for 'Weiter', 'Verlassen', and 'Formular Unterschreiben'.

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

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