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# Patients General Guide for QCMTS ePRO

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Version 01

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## 1. General Information

- The ePRO (electronic patient-reported outcome) system collects patient-reported outcome like questionnaires and diaries by electronic methods in a simple and convenient way for the patient using the internet via smartphone, tablet or computer
- **In case you encounter difficulties in operating QCTMS ePRO as intended, please refer to these guidelines or contact your study physician for further assistance.**
- During the activation of the patient you have to create a personal PIN to request a session code for further data entries. Your PIN should not be shared with anyone.
- Data should be entered into ePRO in local language and within given time frame. All questions on each block should be answered unless instructed otherwise.
- Please avoid the use of abbreviations and acronyms. Don't use ditto marks, arrows, or 'same as above' notations in data fields.
- Please do not leave blanks, to get a complete questionnaire. For missing data or data that can't be obtained at that moment and has to be entered/changed later, please save the section and enter this data in the given revision time.
- All required questionnaire fields are displayed in bold. An alert message reminds you, that saving will be impossible until the required questions have been answered. A questionnaire with missing required fields can't be submitted.
- If you have finished your data entry, please log out to protect your privacy.



## 1.1 Activate the account

- During your first study visit your physician will create a patient account for you within QCTMS ePRO.
- At this point you have to decide if you want to be contacted via SMS or email. Corresponding data has to be deposited for your account.
- Once your account has been registered by your physician you will receive a first welcome SMS / email with the link to **activate your account** (1).
  - You only have to perform the account activation once at the beginning and in case your account has to be reset.

Welcome to QCTMS ePRO!

To activate your account you have to confirm your data with your e-mail address, specified in your ePRO patient documentation. Please create a personal PIN during activation, to obtain your session codes in future. Please ensure that you will not forget your personal PIN.

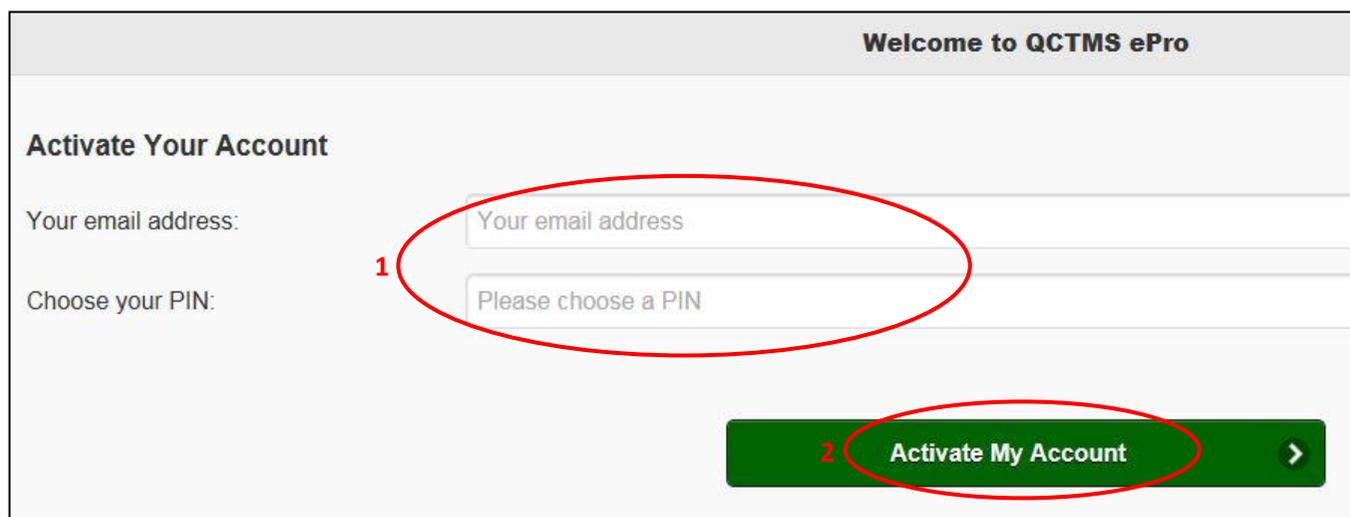
Please use this link to activate your account:

1 <https://epro.qctms.de/sis/QdQwM6>

This app has been developed to make data recording as easy and comfortable as possible for patients within medical studies.

## PATIENTS GENERAL GUIDE FOR QCTMS EPRO – V01

- Select the link and insert your telephone number / email address and create a personal PIN with 4 characters and/or numbers (1).
- Please make sure you do not forget your PIN. You will need it for every login. **In case you do not remember your PIN, contact your study physician to reset your account.**
- Please select **Activate My Account** (2).



Welcome to QCTMS ePro

**Activate Your Account**

Your email address:

Choose your PIN:

2 **Activate My Account** >

- Your account was successfully activated if you see the following message: *Your account has been successfully activated!*



**Sign in**

Your account has been successfully activated!

## 1.2 Login to QCTMS ePRO

- After activating your account, you will receive an email or SMS with a link to request your **Session-Code** (1).

Your QCTMS ePRO account has been activated successfully. Please use following link to request a session code with your PIN:

1 <https://epro.qctms.de/su/login/99353edd812043fb9d486cce538a8376>

Please add this link to your browser favorites to request further session codes.

This app has been developed to make data recording as easy and comfortable as possible for patients within medical studies.

- Select the link and a new web site will open in your browser on your computer/smartphone.
- Please select **Sign in** (2) and a new window will open.





### Step 1/2: Request Session-Code

To protect your privacy, each login requires a single use Session-Code!

Please enter your PIN:

**1** Request new Session-Code

- Please enter your previously created **PIN** and select **Request new Session-Code (1)**.

### Sign in

We have send you an email with a new secure Session-Code!

- You will receive a new **session code** via email / SMS.

Your QCTMS ePro Session-Code: 84134

This code is valid for 1 login until:  
Dec. 2, 2016, 12:09 p.m.



**Step 2/2: Sign in**

Please enter your Session-Code: .

**1**

- Please enter your **Session-Code** and select **Sign in** (1).
- You will be redirected to your personal **Dashboard**.
- If your questionnaires are not released yet, you will see the note: *Well done, currently nothing to do.*

**Dashboard** ☰

**Session: 09:37**

logged in as: **BT\_003**

Well done, currently nothing to do!

**Please note:**  
 If no activity is recorded in the system for 10 minutes, your account will be locked automatically.  
 In that case you have to request a new session code to continue answering the questionnaire.

## 2 Dashboard

- The Dashboard is the surface for all available questionnaires.



### 2.1 Accessing Questionnaires

- In the section **Active** you will find all active questionnaires with the number of questions and how much time you have to finish it.
- If you want to start the questionnaire, please select the green **Start** button (1).



- In the section **Occasional Questionnaires**, you will find, if supported in your study, questionnaires with a special indication, which can be answered every time the indication is fulfilled.
- If you want to start an occasional questionnaire, select the green **Enter** button (1).



**Occasional Questionnaires**

Event	Indication	
Quality of Live EQ - 5D	Please fill out an occasional Event, if there are serious changes in your daily health state	1

- In the section **Revision** you will find completed questionnaires which can still be changed as well as the number of answered questions, the date submitted and the remaining revision time.
- These questionnaires can be updated by you until the end of the revision time.
- If you want to change data within the submitted questionnaire, please click on the white **Edit** button (2).

**Revision**

Questionnaire	Progress	Submitted	Revision till	
Asthma Diary	11 of 11 questions	Nov. 30, 2016, 4:23 p.m.	Dec. 3, 2016, midnight	
Asthma Control Test	7 of 7 questions	Nov. 30, 2016, 4:22 p.m.	Dec. 6, 2016, midnight	2

## 2.2 Types of Questions

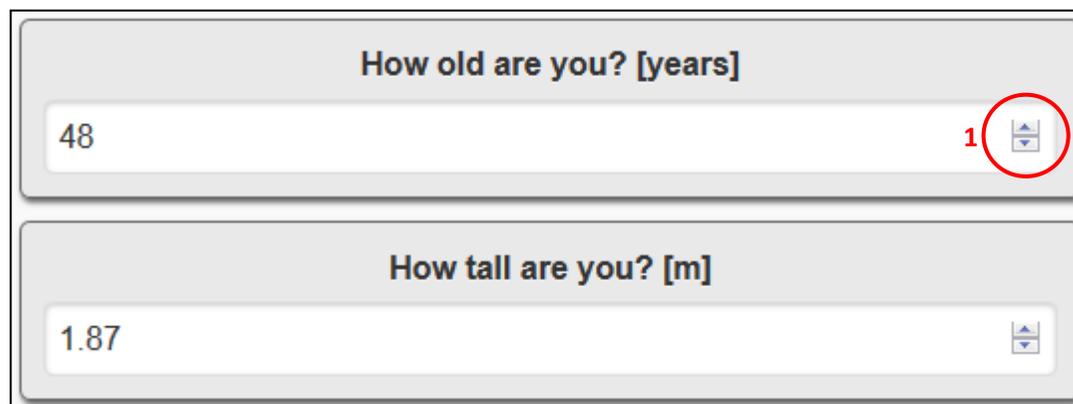
- Within the questionnaire provided to you for the study you are participating in, there may be one more types of questions that you should answer. The following question types may be present:
  - Text questions
  - Numerical questions
  - Visual analog scale (VAS) questions
  - Checklist questions
  - Single choice list questions

- For **text questions**, you may provide an answer in a written form without selecting answer options.
- Text questions can also be used to record date or time formats. In these cases, a specific format will be required (e.g. dates in DD-MMM-YYYY format). In case the text you entered does not match the desired format, a reminder message will be displayed.

List any negative health symptoms you are experiencing

Do you have high blood pressure, asthma or colitis?

- For **numerical questions**, only numbers are allowed as answers.
  - These may either be whole numbers (e.g. age in years) or numbers containing one or more digits (e.g. height in meter).
  - Sometimes, there is a minimum and/or maximum value that may be entered. A reminder message will appear in case the entered value is outside of the desired range.
- To answer numerical questions, select the answer field and enter a number.
  - Alternatively, you may select the up and down arrows on the right side (1) to select a number.
  - You may also use the mouse wheel to adjust the number.
  - Please provide the answer in the specified unit (e.g. years or meter)



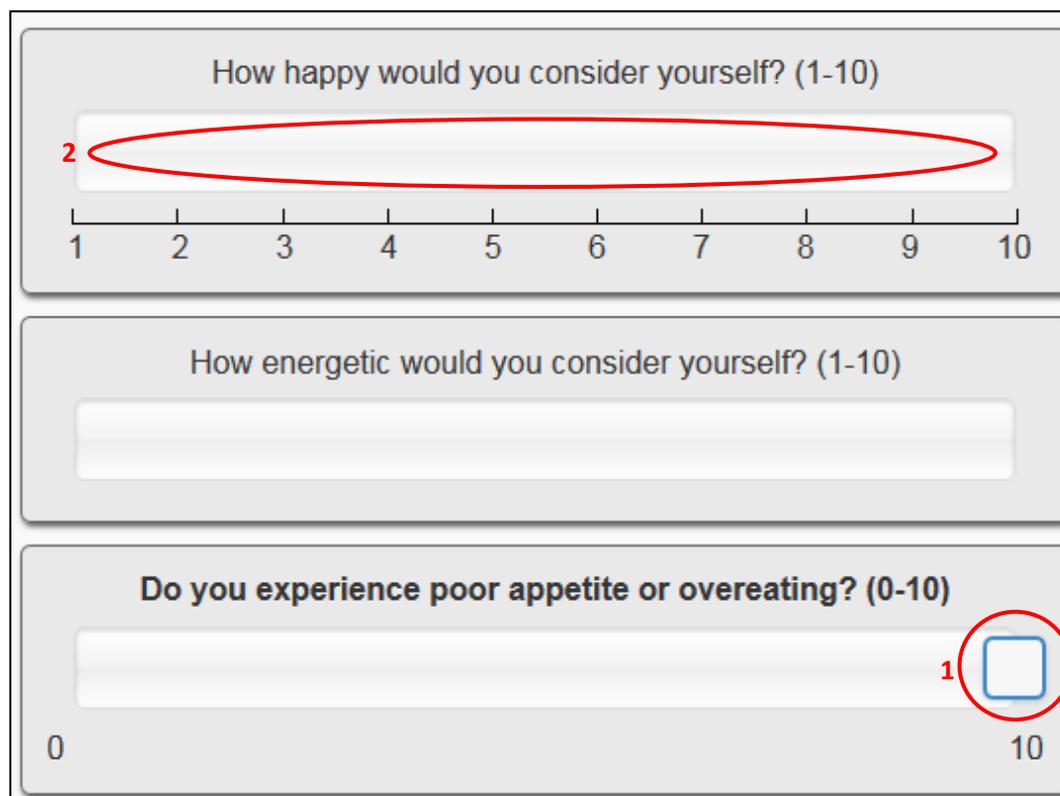
How old are you? [years]

48 1

How tall are you? [m]

1.87

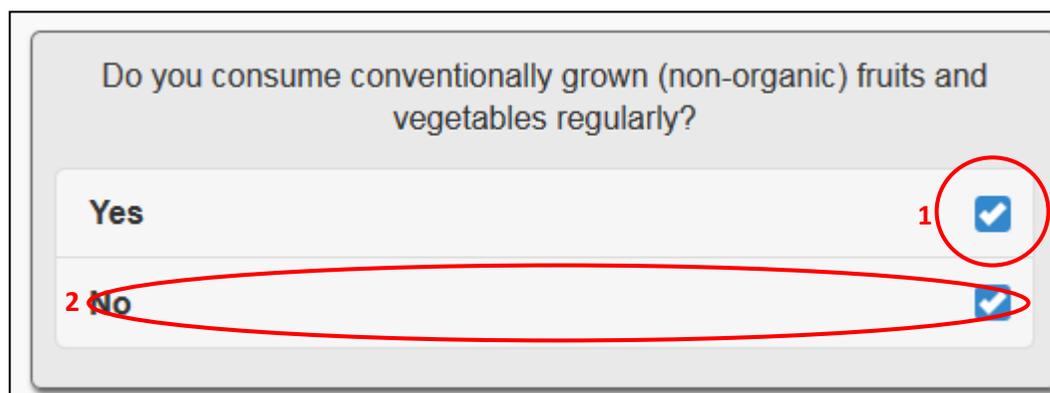
- For **VAS questions**, an answer has to be selected on a scale.
  - The scale may either have a minimum and maximum value, no value or values in regular intervals.
  - A square (1) indicates your current selection. The square may either be present from the start or it will appear after your first selected an answer.
- To answer VAS questions, select somewhere on the scale (2).
  - You may change your answer by selecting and moving the square indicating your current answer.
  - Alternatively, you may change your answer by selecting a different value on the scale.



The image displays three Visual Analog Scales (VAS) for patient assessment. Each scale consists of a horizontal bar with numerical markers at the ends and a small square marker indicating the current selection.

- Scale 1:** "How happy would you consider yourself? (1-10)". The scale ranges from 1 to 10. A red oval highlights the number 2 on the scale, indicating the current selection.
- Scale 2:** "How energetic would you consider yourself? (1-10)". The scale ranges from 1 to 10. No selection is currently visible.
- Scale 3:** "Do you experience poor appetite or overeating? (0-10)". The scale ranges from 0 to 10. A blue square marker is positioned at the 10 mark, with a red circle highlighting it and the number 10.

- For **Checklist questions**, one or more answers may be selected out of multiple possible answers options.
  - A blue checkbox indicates an answer has been selected (1).
- To answer checklist questions, click anywhere on the answer choice field of the answer you wish to select (2).
  - You may deselect your answer by selecting the same answer choice field again.



Do you consume conventionally grown (non-organic) fruits and vegetables regularly?

Yes  1

2 No

- For **Single Choice List questions**, one answers only may be selected out of multiple possible answers options.
  - A blue circle (1) or the displayed answer (2) indicate an answer has been selected.
- To answer single choice list questions, click anywhere on the answer choice field of the answer you wish to select (3) or select the dropdown menu and one of the possible answers (4).
  - You may change your answer by selecting another answer.

Do you consume conventionally raised animal products (meat, dairy, eggs) regularly?

Yes 1

3 No

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Do you consume fish or seafood more than twice a week? If so, please describe what you eat and whether it is farmed or wild

Please choose...

Please choose...

Yes 4

No

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Do you consume fish or seafood more than twice a week? If so, please describe what you eat and whether it is farmed or wild

2 Yes



## 2.3 Pending Questionnaires

**Dashboard** 1

Session: 09:37

- 2 Pending Questionnaires
- Submitted Questionnaires
- Logout

- If you select the **Menu** button (1) you will have the possibilities to view pending questionnaires.
- Select **Pending Questionnaires** (2).

- In the section **Pending Questionnaires** you will find pending questionnaires that have already been scheduled for you as well as the information when these become available and in which timeframe you should complete them.
- Most questionnaires have to manually be activated for you by your physician and will therefore not appear in this list.

Pending		
Start	Questionnaire	Proceed
Tomorrow	Asthma Diary	Dec. 3, 2016, midnight - Dec. 4, 2016, midnight
In 2 days	Asthma Diary	Dec. 4, 2016, midnight - Dec. 5, 2016, midnight



## 2.4 Submitted Questionnaires

**Dashboard**  
Session: 09:37

- 1
- 2 **Pending Questionnaires**
- Submitted Questionnaires**
- Logout**

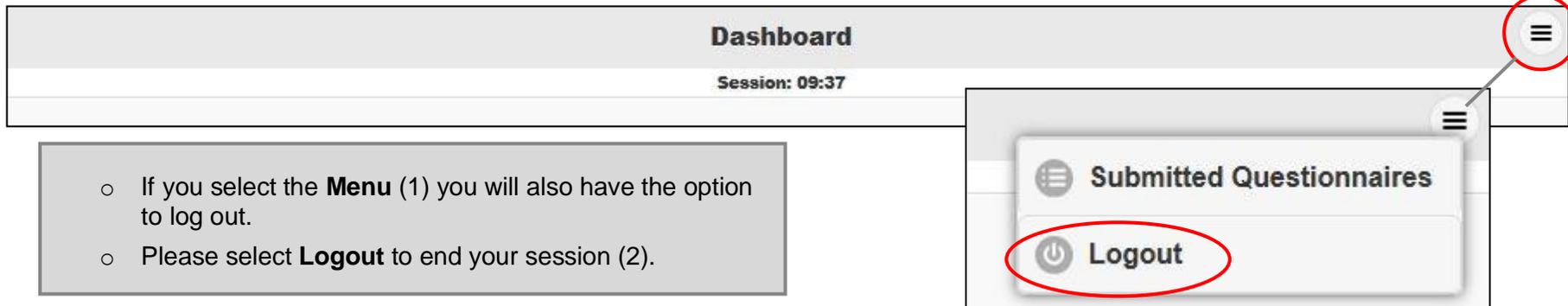
- If you select the **Menu** (1) you will have the option to view your submitted questionnaires.
- Select **Submitted Questionnaires** (2).

- In the section **Submitted Questionnaires** you will find completed questionnaires with the number of answered questions and the date submitted.
- These questionnaires cannot be updated as the revision time has passed.
- If you wish to view your provided answers, select the white **View** button (3).

**Submitted Questionnaire (Page: 1)**

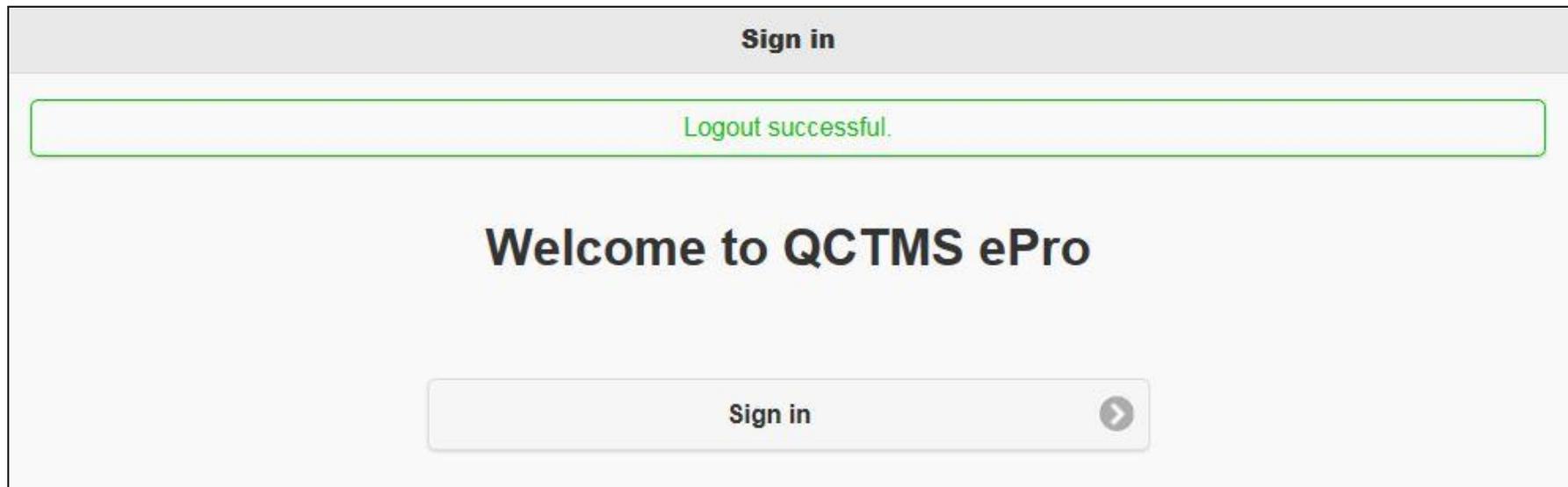
Questionnaire	Progress	Submitted	
Asthma Diary (Nov. 30)	11 of 11 questions	Nov. 30, 2016, 4:23 p.m.	<b>View</b>
Asthma Control Test	7 of 7 questions	Nov. 30, 2016, 4:22 p.m.	<b>View</b>

## 2.5 Logout



The screenshot shows the 'Dashboard' header with a session timer at '09:37'. A menu icon (three horizontal lines) is circled in red in the top right corner. A dropdown menu is open, showing 'Submitted Questionnaires' and 'Logout'. The 'Logout' option, which includes a power icon, is also circled in red.

- If you select the **Menu** (1) you will also have the option to log out.
- Please select **Logout** to end your session (2).



The screenshot shows the 'Sign in' page. A green message box at the top reads 'Logout successful.'. Below this, the text 'Welcome to QCTMS ePro' is displayed in a large font. At the bottom, there is a 'Sign in' button with a right-pointing arrow.

- If you accidentally logged out, you have the possibility to request a new **Session-Code** by selecting **Sign in** (3) and following the steps described in 1.2 **Login to QCTMS ePRO.**



## Appendix

### General points to consider

- **In case you require assistance with operating QCTMS ePRO, please contact your study physician.**
- Try to answer all question within a questionnaire.
- Data should be entered within the given time frame.
- Please avoid the use of abbreviations and acronyms.
- Do not use ditto marks, arrows, or 'same as above' notations in data fields.
- For data that cannot be obtained at that moment and has to be entered/changed later, please save the section and enter this data until the end of the given revision time.
- All required questionnaire fields written in bold have to be filled. An alert message reminds you, that saving will be impossible until these details have been entered. A questionnaire with missing required fields cannot be submitted.
- After finishing your data entry, you should log out.
- Opening several browser windows / tabs with QCTMS ePRO will only open one session at a time. If ePRO does not behave as expected, try to close all open browser windows first.

### General information

- **Login-page:**  
<https://epro.umws.de/su/login/xx>  
 Whereby the last 32 characters are your personal login link
- **First login:** Please activate your account with your telephone number/email address that you provided to your doctor and create a personal PIN.
- **PIN:** The PIN has four characters and/or numbers and has to be created during the first activation of your account.
- **Forgot PIN:** Please contact your responsible physician to reset the account. After you have received a new email/SMS to activate the account again, you have to create a new personal PIN.
- **Timeout:** If no activity was recorded within the ePRO system within 10 minutes, you will be automatically logged out from the system for safety reasons. You have to request a new session code to log in again.