



# **secuTrial®-manual**

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## 1. Introduction

This manual is intended to make it easier for you to use secuTrial® DataCapture. With the DataCapture you can enter and manage patient data.

### 1.1. System requirements

The secuTrial® DataCapture can be accessed under a wide variety of operating systems (e.g. Windows, MacOS or Linux). In order to work with the secuTrial® DataCapture you do not need to install any special software on your computer. The software required for the tool is installed on a central server. To access it, simply use one of the popular browsers (Microsoft Internet Explorer, Google Chrome, Mozilla Firefox, Safari, etc.).

JavaScript and SSL encryption must be enabled in your browser and MetaRefresh must be allowed. ActiveX can be disabled. If you do not want to handle DICOM images, you can also deactivate Java. For security and privacy reasons, the cache should be set to zero. Pop-up suppression, if the browser offers it, must be deactivated. If you need support regarding the browser settings, please contact your local system administrator.

### 1.2. General user information

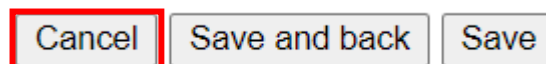
The DataCapture is accessed via Internet. Slow, insecure or unstable Internet access will inevitably result in limited system performance. The URL (=Internet address) to be used for logging in to DataCapture as well as your access data (user ID / password) were sent to you by e-mail from the data storage in Göttingen. If this is not the case, please contact the study director.

Depending on the browser you are using, the window view, menu or print layout may vary slightly. All functions of the DataCapture have been tested with common browsers. Please never use the browser functions "Reload", "Back", "Forward", but only the navigation areas of secuTrial® (Fig. 1).

Time left: 55:42  
| Reload | Help | Logout

*Fig. 1: Navigation areas*

Clicking the CANCEL button (Fig. 2) will take you back to the previous page without saving the entries.



*Fig. 2: Cancel – Button*

By clicking the LOGOUT button you will exit the application. You will have to enter your user ID and password if you want to log in again.

If you have not had any contact with the server for more than 60 minutes, you will be automatically logged out. This ensures that no unauthorized people can gain access to the database and change your records ("Contacting the server" means saving, Changing form pages, but not just entering data into a form).

The remaining time until logout is displayed in red in the title bar of the browser window as well as within the page in the upper status bar. If you are automatically logged out, data that you have not yet saved may be lost. Therefore you should, if you interrupt your work, save the form you are currently working on, (SAVE button) (Fig. 2).

Most pages of the DataCapture have a help function, which you can access with the HELP button in the main menu at the top right. For orientation, the header of all secuTrial® pages always shows the current user data.

Date 27.10.2023 - 12:16 (CEST)  
Participant Karoline Kleber

Fig. 3: User data

## 2. Registration



# DZHK Testsystem

DEUTSCHES ZENTRUM FÜR  
HERZ-KREISLAUF-FORSCHUNG E.V.

English ▾

**Welcome to secuTrial!**  
(Deutsches Zentrum für Herz-Kreislauf-Forschung e. V.)

This area is non-public and accessible to registered participants only.

If you are a registered user, please enter your user-ID and password in the respective fields. When you log in for the first time you will be required to change your password. After this you can change the password when manually using the "Change password" button.

User-ID

Password

secuTrial® 6.4.3.10, 2023

Fig. 4: Login mask

To log in to DataCapture, please use the link sent to you by the data management via email. To log in to DataCapture, enter your user ID and password. Your user ID has been assigned to you together with your password. Please enter your user ID under "User ID". Pay attention to the exact spelling (Fig. 4).

When you log in for the first time, you will be prompted to change your password. Enter your own password and do not share it with anyone else under any circumstances. For security reasons, the new password must meet the following criteria:

- It must have at least 8 characters
- It must contain upper and lower case letters
- It must contain at least one special character (e.g. % + \$ ! ? #)
- The new password must not be the same as the one sent to you

For security reasons, you will be asked to change your password on a regular basis. The new password, must not be the same as the previous one.

## 2.1. Logout

You have to log out manually after each use and when leaving the workstation. (LOGOUT in the upper menu bar), so that no one can use your user account without authorization. After logging out, you will be shown an information page. There you will find a link that will take you back to the login page.

## 2.2. Change password

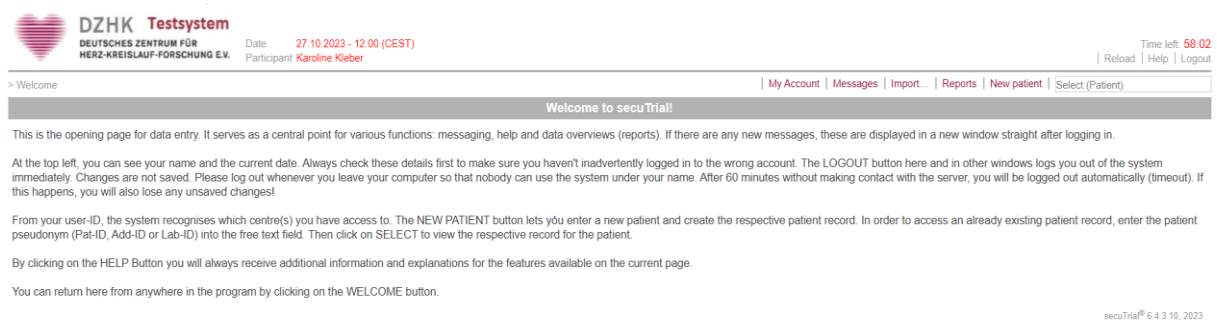
You can change your password any time. Therefore click the „My Account“ on the welcome page. Simply enter your previous password and enter a valid new password twice.

### 2.3. Request new password

If you have forgotten your password, please contact the data management in Göttingen. It will send you a new password by e-mail. Since your request is processed manually this can take up to one working day.

## 3. Welcome page

This is the central access point for the various functions of the application (Fig. 5).



The screenshot shows the 'Welcome' page of the 'DZHK Testsystem'. At the top left is the DZHK logo and name. To the right, it displays the date '27.10.2023 - 12:00 (CEST)' and the participant name 'Karoline Kieber'. On the far right, it shows 'Time left: 58:02' and links for 'Reload', 'Help', and 'Logout'. Below the header is a navigation bar with links: 'My Account', 'Messages', 'Import...', 'Reports', 'New patient', and 'Select (Patient)'. The main content area has a heading 'Welcome to secuTrial!' and several paragraphs of instructions for users, including information about logging out, using the 'NEW PATIENT' button, and the 'HELP' button. The version 'secuTrial® 6.4.3.10, 2023' is noted in the bottom right corner.

Fig. 5: Welcome page

Here you can, depending on the assigned role:

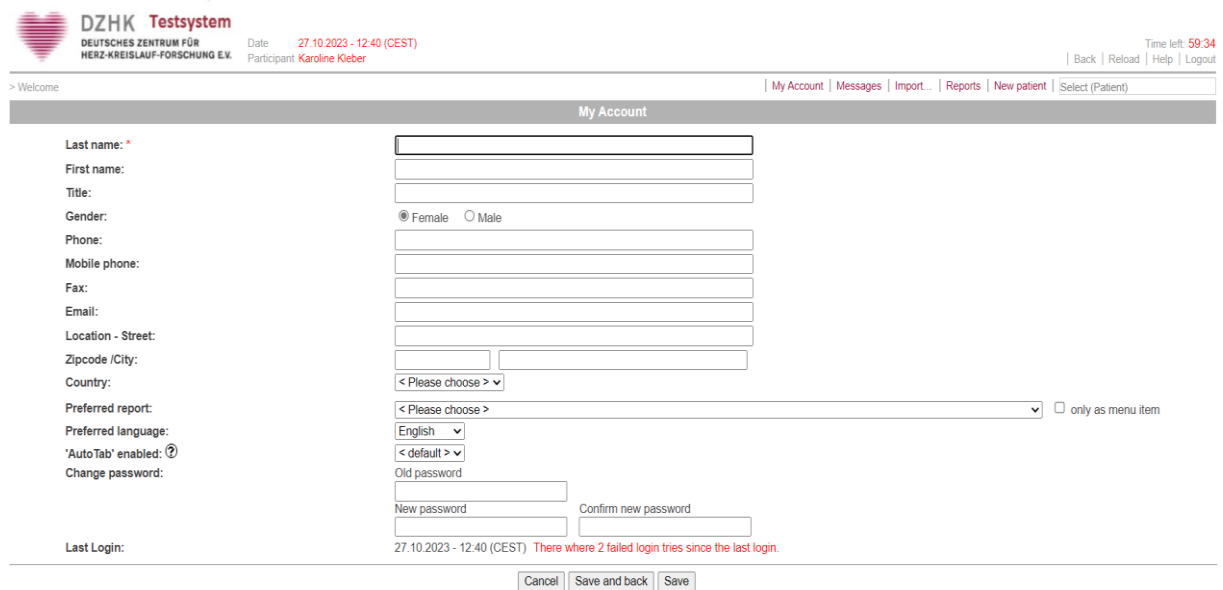
- Retrieve your saved reports (My Reports)
- Access and change your own participant data (MY ACCOUNT)
- View or write messages (MESSAGES)
- Import form data or discrepancies (IMPORT)
- View reports, statistics and patient list (REPORTS)
- Create a new patient (NEW PATIENT)
- Search for an external patient (SEARCH PATIENTS)
- Call up patient data and enter or edit data (SELECT)
- Download documents (DOWNLOAD AREA)



The Welcome page contains general information about using the application. Among other things you can find the contact data of the data management, as well as important information (regular maintenance windows). By clicking the HELP button you will get more detailed explanations about the respective functions. The "Refresh" button ensures that the system is updated or synchronized. With clicking the WELCOME button you come back to this starting position from each page of the DataCapture.

### 3.1. My account

You can set your preferred language using the MY ACCOUNT button (Fig. 6). All buttons and general labels of the applications you have access to will be displayed in the corresponding language. At the moment German and English are offered. If you do not make a selection, the default setting of the project or the current customer will be used. Furthermore, you can change your password, or store your contact details.



**DZHK Testsystem**  
DEUTSCHES ZENTRUM FÜR  
HERZ-KREISLAUF-FORSCHUNG E.V.

Date: 27.10.2023 - 12:40 (CEST)  
Participant: Karoline Kleber

Time left: 59:34  
| Back | Reload | Help | Logout

> Welcome | My Account | Messages | Import... | Reports | New patient | Select (Patient)

#### My Account

Last name: \*

First name:

Title:

Gender:  Female  Male

Phone:

Mobile phone:

Fax:

Email:

Location - Street:

Zipcode /City:

Country:

Preferred report:   only as menu item

Preferred language:

'AutoTab' enabled:

Change password: Old password   
New password  Confirm new password

Last Login: 27.10.2023 - 12:40 (CEST) There where 2 failed login tries since the last login.

Fig. 6: My account view

### 3.2. Add a new patient to the database

To create a new patient in the SecuTrial® system, a client certificate from the DZHK Trust Center is required. The certificate can be applied for analogously to the user accesses in an online form of the trust center Greifswald. You will then receive a client certificate, which will be imported into the browser. Afterwards you can add new patients as follows:

1. Click on the NEW PATIENT button on the Welcome page (Fig.7).

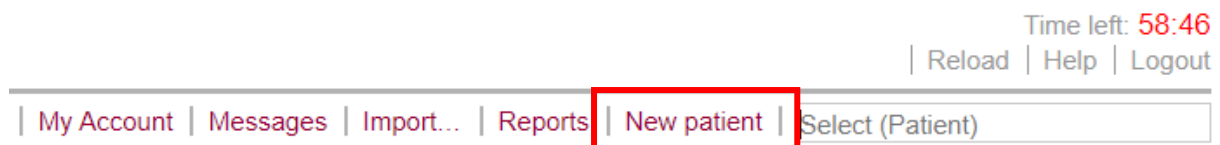


Fig.7: Menu of the welcome page

2. Select a project and a center to which you want to add the patient and enter a Zus ID, if requested. Enter the date of admission and click on continue (Fig. 8).

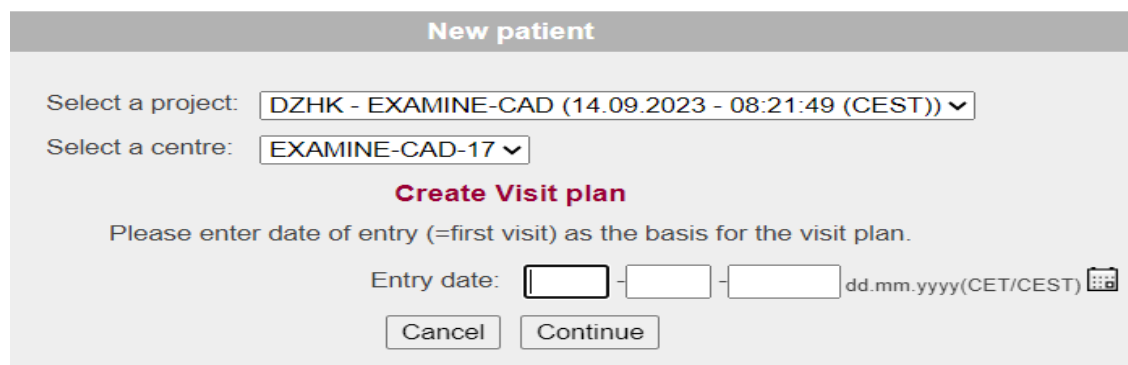
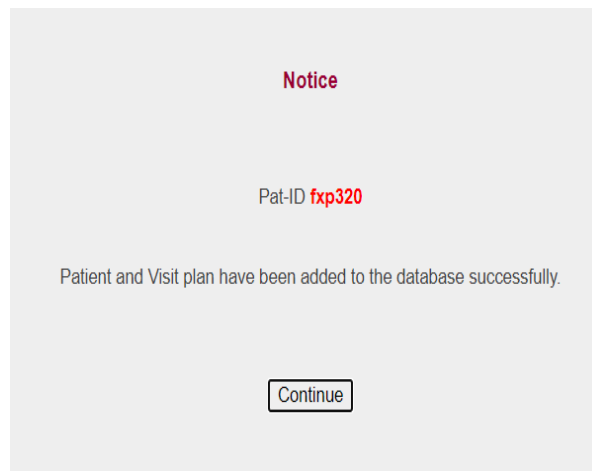


Fig. 8: Create a new patient

3. If it is provided for your study, please select the appropriate certificate for authentication and click OK. If you have any questions about purchasing the certificate please contact your associated office.
4. The patient has been created in SecuTrial® and the created pseudonym is displayed. Click NEXT to go to the visit schedule (Fig. 9).



*Fig. 9: Patient has been created*

5. Within the visit plan (Fig. 10), you can open the individual forms for data entry by clicking on them. Always conclude the data entry via SAVE, otherwise the data you have entered will not be saved.

	Baseline	Start of Immunsuppression	Hospital admission	Implantation	Follow Up 1	Follow Up 2	Follow Up 3	Follow Up 4	Follow Up 5	Next visit
Planned visits	06.01.21	30.01.21	02.02.21	03.02.21	17.02.21	03.03.21	28.04.21	21.07.21	05.01.22	
Data entry	23.03.23	-	-	-	-	-	-	-	-	-
Inclusion and Exclusion Criteria										
Anamnesis an Clinical Diagnosis (incl. Basic Data Set)										
Physical examination										
Laboratory diagnostics										

Fig. 10: Example visit plan

### 3.3. Calling patients/data entry and editing

There are two ways to call up an already created patient:

**1. Enter the patient's pseudonym via the SELECT input button.**

At the top right of the welcome page (Fig. 11). You are then taken directly to the visit plan of the patient

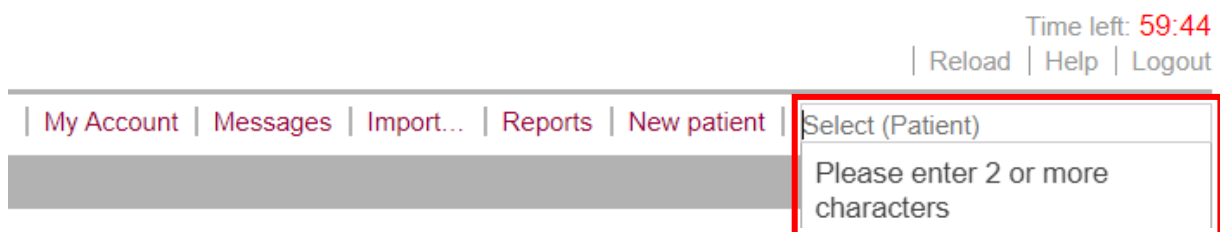


Fig. 11: Call patients – SELECT



**DZHK Testsystem** DEUTSCHES ZENTRUM FÜR HERZ-KREISLAUF-FORSCHUNG E.V. Date: 27.10.2023 - 14:14 (CEST)  
Formular Builder - ohne freigeben: Karoline Kleber  
Project: DZHK - EXAMINE-CAD (14.09.2023 - 08:21:49 (CEST)) Close

Reload | Print

Patientenliste (47 Patients)

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

Filtered by: <no filter set>

Apply | Reset

Patient	Centre	Σ	Screening	Baseline	Visite 2 (Telefon)	Visite 2 (Telefon)	Visite 2 (Telefon)	Visite 3 (vor Ort)	Visite 4 (Telefon)	Visite 5 (Telefon)	Visite 6 (vor Ort)	Visite 7 (Telefon)	Visite 8 (Telefon)	Visite 9 (vor Ort)	Visite 10 (vor Ort)	Visite 10 (vor Ort)	Visite 10 (vor Ort)	Studienende	Studienmedika
ads814 (105)	UMG_EXAMINE																		
bhn396 (107)	UMG_EXAMINE																		
bth346	EXAMINE_Test																		

Fig. 14: Patient list

The form overview (Fig. 15) is the central starting point for entering or editing patient data. The icons give you a quick overview of the status (see Chapter 3.3.3. Status and help) of the various forms and form families.

**DZHK Testsystem** DEUTSCHES ZENTRUM FÜR HERZ-KREISLAUF-FORSCHUNG E.V. Date: 27.10.2023 - 14:18 (CEST)  
Formular Builder - ohne freigeben: Karoline Kleber  
Project: DZHK - EXAMINE-CAD (14.09.2023 - 08:21:49 (CEST)) Centre: UMG\_EXAMINE  
Patient Pat-ID: ads814 Rand-No: 105 (02.03.22) Time left: 58:46  
Welcome | Reload | Help | Logout

> Welcome > Patient ads814 Patient .. | New patient | Select (Patient)

Visit plan | Adverse Events (1) | Studienende | Studienmedikation | Begleitmedikation | Protocol Deviations

Planned visits	Screening 05.05.21	Baseline 05.05.21	Visite 2 (Telefon) 19.05.21	Visite 3 (vor Ort) 02.06.21	Visite 4 (Telefon) 16.06.21	Visite 5 (Telefon) 30.06.21	Visite 6 (vor Ort) 14.07.21	Visite 7 (Telefon) 28.07.21	Visite 8 (Telefon) 11.08.21	Visite 9 (vor Ort) 25.08.21	Visite 10 (vor Ort) 01.09.21
Visitenregistrierung											
Ein- und Ausschlusskriterien											
Randomisierung											
Anamnese und Diagnosen											
Labordiagnostik											
Körperliche Untersuchung											
Herzkatheter Befund											
Imaging Corelab - Herzkatheter											

Fig. 15: Form overview

A form family can contain one or more forms. If a form family contains only one form it will be opened directly after clicking the icon of the form family. If it contains multiple forms, an overview of the forms is first displayed in the footer of the page (below the frame) (Fig. 16). Click on the form family icon again to close it. To open a single form click again on the corresponding icon below. The individual forms can usually be opened and edited in any order.



Fig. 16: Form family with multiple forms

The HELP button in the form overview provides you with an overview of the icon representations and meanings (see chapter 3.3.3. Status and Help). In the header of the DataCapture (Fig. 17) your name, project, date, center and pseudonym(s) must be displayed correctly. Navigation buttons that allow you to return to the Welcome page (WELCOME) or to log out of the system (LOGOUT) are located in the main menu at the top right of the page.



Fig. 17: Form header

### 3.3.1. Create a new visit

If you want to enter data for a new visit, click the NEW VISIT button (Fig. 18). If different visit types (planned and unplanned) are specified for the current project in the visit plan template, you now have the following options to select one of the types (Fig. 19).

	Visit plan	AE/SAE	Hospitalisation in case of heart failure	Concomitant medications	Concomitant therapy	Protocoldeviation	End of study					
			Baseline	Start of Immunsuppression	Hospital admission	Implantation	Follow Up 1	Follow Up 2	Follow Up 3	Follow Up 4	Follow Up 5	Next visit
Planned visits			30.12.20	23.01.21	26.01.21	27.01.21	10.02.21	24.02.21	21.04.21	14.07.21	29.12.21	
Data entry			20.01.21	-	-	-	-	-	-	-	-	


Fig. 18: Link to create a new visit



**Next visit**

Please specify if the next visit is a regular or unscheduled visit in compliance with the study protocol.  
Unscheduled visits are ignored during the generation of the regular visit plan.

Unscheduled visit: **USV Follow Up**

Date:  -  -  dd.mm.yyyy(CET/CEST) 

*Fig. 19: Input field visit date*

Depending on the settings of the study, it may be possible to create visits in non-chronological order. The internal numbering of the visits is carried out in the order in which they were created. The display in the form overview remains strictly chronological. For each new visit, a new set of forms is made available, which you can open via the corresponding icons. The forms associated with each visit are already stored in the system.

### 3.3.2. Modification of an existing visit

The admission date and the scheduled visit date of all visits can generally be edited, if the right to edit and display the VISIT PLAN button has been configured for the current role. Either all visits or only individual visits can be edited. The editing is logged with a reason to be entered in the visit plan history.

**Important:** Changes to the visit schedule are only possible as long as no data has been saved in the visit forms!

To change the visit date and visit type, please click on the PATIENT link and then on EDIT VISIT PLAN (name may vary depending on configuration) (Fig. 20).

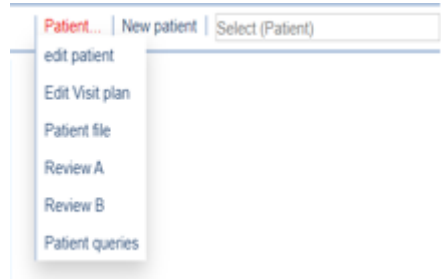


Fig. 20: Link edit visit plan

When the visit date of all visits is changed, all subsequent, scheduled visits will be shifted by the date change as long as the date of a subsequent visit has not been changed itself. In this case, the shift is recalculated and carried out from the changed visit date. Unscheduled visits are not affected by the planned visits. They can be postponed independently. If no data has been collected, they can be deleted in any order (Fig. 21).

**Edit Visit plan**

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

shift subsequent visits accordingly   
  only edit individual visits

Entry date	05.05.2021 (CEST)	05	-05	-2021	dd.mm.yyyy(CEST/CEST)	
		Visit date				Hide
Screening	05.05.2021 (CEST)	05	-05	-2021	dd.mm.yyyy(CEST/CEST)	<input type="checkbox"/>
Baseline	05.05.2021 (CEST)	05	-05	-2021	dd.mm.yyyy(CEST/CEST)	<input type="checkbox"/>
Visite 2 (Telefon)	19.05.2021 (CEST)	19	-05	-2021	dd.mm.yyyy(CEST/CEST)	<input type="checkbox"/>
Visite 3 (vor Ort)	02.06.2021 (CEST)	02	-06	-2021	dd.mm.yyyy(CEST/CEST)	<input type="checkbox"/>
Visite 4 (Telefon)	16.06.2021 (CEST)	16	-06	-2021	dd.mm.yyyy(CEST/CEST)	<input type="checkbox"/>
Visite 5 (Telefon)	30.06.2021 (CEST)	30	-06	-2021	dd.mm.yyyy(CEST/CEST)	<input type="checkbox"/>
Visite 6 (vor Ort)	14.07.2021 (CEST)	14	-07	-2021	dd.mm.yyyy(CEST/CEST)	<input type="checkbox"/>
Visite 7 (Telefon)	28.07.2021 (CEST)	28	-07	-2021	dd.mm.yyyy(CEST/CEST)	<input type="checkbox"/>
Visite 8 (Telefon)	11.08.2021 (CEST)	11	-08	-2021	dd.mm.yyyy(CEST/CEST)	<input type="checkbox"/>
Visite 9 (vor Ort)	25.08.2021 (CEST)	25	-08	-2021	dd.mm.yyyy(CEST/CEST)	<input type="checkbox"/>
Visite 10 (vor Ort)	01.09.2021 (CEST)	01	-09	-2021	dd.mm.yyyy(CEST/CEST)	<input type="checkbox"/> Delete

Fig. 21: Site edit visit plan

When changing the visit plan, a reason must be specified for saving. This reason is listed in the visit plan history.

### 3.3.3. Status and help

The filling status of the forms (empty, partially filled or completely filled) is indicated by a color gradation of the icons. Clicking the HELP button on the form overview of a patient opens a window with the page "Help - Form overview". Here you can read the meaning of the symbols (Fig. 22).

| Print | Close












Help - Form overview		
Icon	Status	Description
	without db-table	These forms will not be stored in the database.
	not stored	No data has been entered yet.
	empty	The form has been saved empty. In the form family at least one form has been stored empty.
	partially filled	At least some data has been entered but not all mandatory fields have been filled.
	completely filled	All mandatory fields have been filled.
Color	Status	Description
	standard form	Used for the capture of normal data.
	Adverse Event form	For capturing data during the workflow of Adverse Events.
	Serious Adverse Event form	For capturing data during the handling of Serious Adverse Events.
Symbol	Status	Description
	validation	The rule validation of this form finished with problems (warning, error).
	comment	At least one comment has been posted.
	open query	At least one query is open. Queries can relate to individual forms or to higher-level structures such as visits or even the entire patient.

Fig. 22: Help – window with explanations regarding the form icons

### 3.3.4. Project selection

If a patient is included in several studies, you can switch between different subprojects, use the selection list on the right side (in the frame around the form icons). This will only be displayed if the patient is included in more than one subprojects and if the corresponding rights have been activated for you.

## 3.4. Reports and statistics

If you click on the REPORTS button in the main menu, you will get an overview of all the reports and statistics created for your project, which you can view according to your rights. The preferred report defined for a participant (editable under My account - Preferred Report) will be displayed on the Welcome, Form Overview and Form page as an additional menu button. When clicked, the preferred report will be opened in an additional popup and can be used to navigate between patients. Immediately after logging in, your preferred report will open in a popup. If you would like the report only be displayed as a menu selection, you can configure this under My account.

### 3.4.1. Reports

After selecting an individual report by clicking on the title, it opens in a separate window and you can get an overview of all patients (or results) of the centers assigned to you. In most cases, an entry (line) is displayed for each patient included in the report. Reports are always displayed in a separate report window, which is independent of other windows. The report window remains open even if you open an additional window in the form view, e.g. for editing queries. All reports are always opened in the same window.

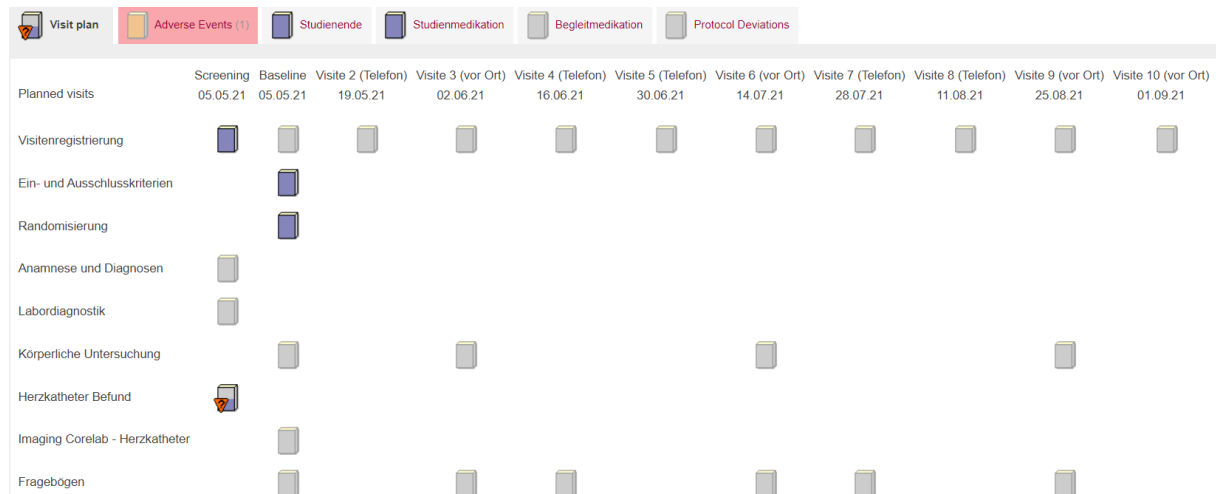
If a help text has been specified for a report in the FormBuilder, a help button is displayed in the report window in the menu. This button opens another small popup with the defined help text.

### 3.4.2. Statistics

After selecting a single statistic, it will open in a separate window and you will get a graphical representation of the totals of the patients with a defined indication. Summaries of patient data are displayed and not individual patients. After view you can print the statistics with the PRINT button and close the window with the CLOSE button.

## 4. Enter patient data

Clicking the form icon in the form overview opens the stored form for data entry (Fig. 23).



	Screening 05.05.21	Baseline 05.05.21	Visite 2 (Telefon) 19.05.21	Visite 3 (vor Ort) 02.06.21	Visite 4 (Telefon) 16.06.21	Visite 5 (Telefon) 30.06.21	Visite 6 (vor Ort) 14.07.21	Visite 7 (Telefon) 28.07.21	Visite 8 (Telefon) 11.08.21	Visite 9 (vor Ort) 25.08.21	Visite 10 (vor Ort) 01.09.21
Planned visits											
Visitenregistrierung											
Ein- und Ausschlusskriterien											
Randomisierung											
Anamnese und Diagnosen											
Labordiagnostik											
Körperliche Untersuchung											
Herzkatheter Befund											
Imaging Corelab - Herzkatheter											
Fragebögen											

Fig. 23: Visit plan – open form

Once a form has been filled out, it is essential that you click SAVE so that the data is sent to the secuTrial® database. Otherwise the data entered so far will not be saved


When editing larger forms, it is recommended to save the captured data regularly to avoid data loss due to timeouts. If you have entered the data correctly and have saved the form, you will receive a corresponding confirmation. Below the form you will see the author, the date, the reason and if applicable, the validity of the signature from the last saving process. On the confirmation page you can decide whether you want to go directly to the next form, back to the current form or back to the form overview.

### *Notifications*

- The navigation keys (WELCOME, HELP, LOGOUT, etc.) are displayed in the main menu at the top right.
- Additional buttons PRINT, QUERY, COMMENTS refer to the opened form.
- PRINT can be used to print the current form version, that has been saved latest in the data base (!).
- The QUERIES and COMMENTS buttons can be used to display queries and comments for the current form, as far as the corresponding permission has been granted.
- Additional buttons are available at the bottom of the page: CANCEL is used to leave the form without saving any changes to the medical data. SAVE saves the entered data in the secuTrial® database.
- You do not have to fill out a form completely every time. It is possible to enter data and store partial information provisionally, i.e. you can continue with the data collection at a later time. The fields that require an entry are marked (see below) or show a corresponding note when saving.
- Some elements may be marked with a red asterisk \* (Fig. 24). Questions marked in this way are mandatory fields. The form cannot be saved until these fields are filled in.
- In some cases, elements are marked with a \* or two black stars \*\* (Fig. 25). These are elements that cannot be changed due to DZHK harmonization procedures.
- If another participant has already opened the form, it is locked and no data can be entered. In this case, a note will be displayed (Fig. 26).

I. **Was the echocardiography performed?\***  yes  no  unknown  not assessed \*

Fig. 24: Items for which an input is necessary

II. **Date of examination** -- dd.mm.yyyy   unknown  not assessed (\*)

III. **Quality level\***  \*

Fig. 25: DZHK harmonized Items

Anmerkung: Gibt es die Möglichkeit, dies ohne meinen Namen anzuzeigen?

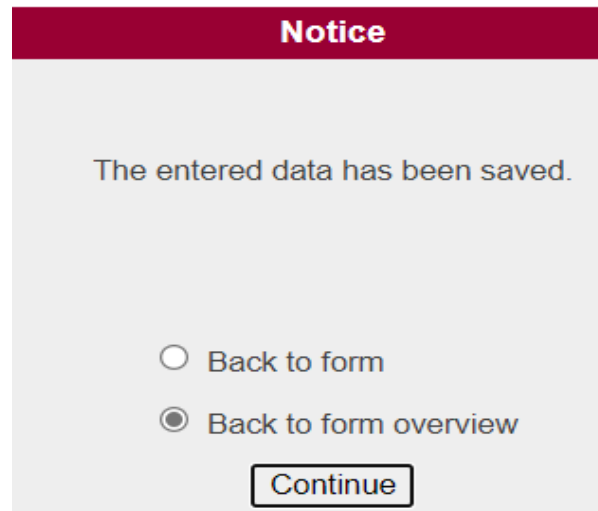


> Welcome > Patient ads814 > Visite 6 (vor Ort) > Visitenregistrierung

**This patient is currently locked by user Karoline Kleber, therefore editing is impossible.**

Fig. 26: Error message

**Important:** Please note that the data will only be saved if the note below appears! You can decide how to continue, e.g. whether you want to return to the form, edit the next form or switch back to the form overview (Fig. 27)



*Fig. 27: Note message*

#### 4.1. Plausibility check

In order to minimize the probability of incorrect entries in the secuTrial® DataCapture and thus to increase the data quality, various data checking functions have been integrated. These alert you to any incorrect data when you attempt to save a form.

As a rule, data formats are checked (e.g., you cannot enter February 30 as the date), logical plausibility (e.g., pregnancy only in female patients), and Threshold values (e.g. a pulse of over 250 is unlikely).

If there are problems with the data that cannot be solved during the data collection, but you still want to continue with the data acquisition, you have the possibility to switch off the plausibility check (after appropriate configuration in FormBuilder).



You can do this by disable the "Check details" checkbox next to the SAVE button. This can also be useful for long forms where you need to interrupt the data input but you can't save the form in this state because a rule check prevents it. However, disabling it should not be the rule, but the exception. Yet, even then you cannot save incorrect formats (e.g. letters in number fields). Error messages bypassed in this way are displayed by a red exclamation mark next to the form icon.

#### 4.2. Summary: Steps for data collection in the forms

1. Click the icon of the form on the form overview that you want to edit.
2. Enter the data in the fields provided.
3. If necessary, enter comments and questions (see chapter 6.2).
4. Save the entries with SAVE, or SAVE AND PRINT if a printout is required
5. The data entry is confirmed. You can now select whether you want to edit the subsequent form or return to the form overview.

#### 4.3. Dealing with missing values

The secuTrial® database forms contain different types of questions or different form components (see chapter 5). For either-or questions (radio button), you can also answer UNKNOWN and NOT RESOLVED. The UNKNOWN option indicates that the value is not known (Fig. 28). For example, a cardiopulmonary exercise test was performed, but the date of the test is not known, so the date would be "unknown". The option NOT RECORDED indicates that a value was not recorded because the question is not applicable. For example, a patient did not have cardiopulmonary exercise testing, so no examination date was recorded.

1.2.1. Sinus rhythm   yes  no  unknown  not assessed \*

Fig. 28: Radiobutton „unknown“ and „not assessed“ options

If the form component to be filled in is not an either-or question, but e.g. a date field, the answer options UNKNOWN and NOT ASSESSED are not displayed right next to the the input field. Instead, the input field contains a circle with a check mark (Fig. 29). Clicking on this icon opens a new window. In this window you can indicate whether the value is unknown or has not been recorded (missing value).


II. Date of examination  -- dd.mm.yyyy 

Fig. 29: Data field with missing values

If you neither enter the date nor specify a missing value for a date field, you will get an error message when you try to save the form. If you still want to save the form even though you have neither entered the date nor specified a missing value, you can uncheck the CHECK DATA checkbox at the bottom of the currently opened form (Fig. 30). You can do this by clicking the check mark in the box next to "Check data". The check mark disappears and the checkbox is deactivated. Please note, here no missing values as well as no other rules of the form will be reviewed when saving.

Check data

Fig. 30: Check data

## 5. Form components

The data input into the forms is done by means of different functions depending on the type of the question. The operation of most elements should be familiar to you from the form input on the Internet. However, there are some combined fields in secuTrial® which offer additional functionalities.

### 5.1. Simple form components

You can enter any text in text fields. The text length is limited to the displayed length (Fig. 31).

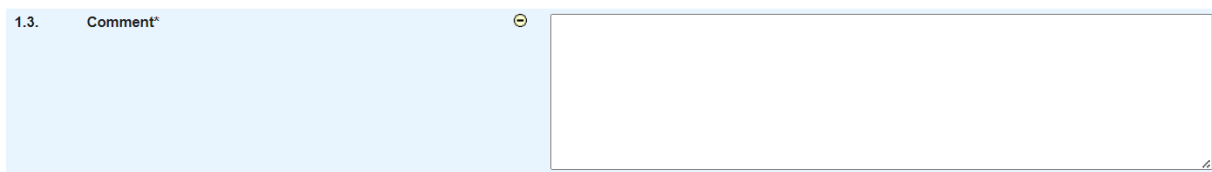


Fig. 31: Text field

Number or date fields restrict data entry to digits and valid dates or times. Some date fields have to be filled in completely, for others you can omit the smaller information (e.g. the day of day-month-year). The required format is displayed to the right of the field. With the help of a calendar next to the field, the date can be quickly searched for and transferred to the field (Fig. 32). Decimal places are indicated by a second number field (Fig. 33).

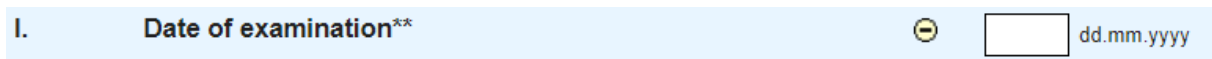


Fig. 32: Date field with format and calendar

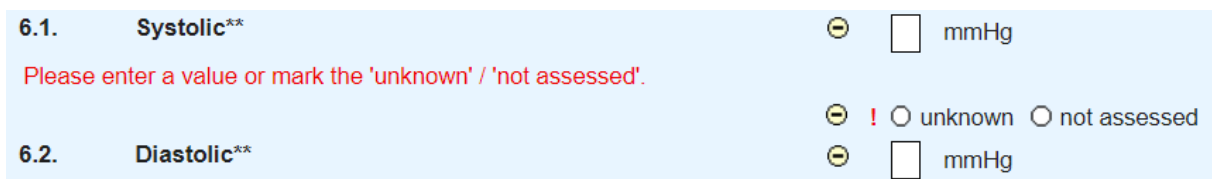
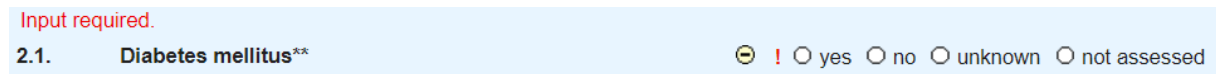


Fig. 33: Data fields with unit

The radio button is applied to either-or questions, you can only give one possible answer. By double-clicking on the selected field you can unselect it (Fig. 34).



Input required.  
2.1. **Diabetes mellitus\*\***   yes  no  unknown  not assessed

Fig. 34: Radio button

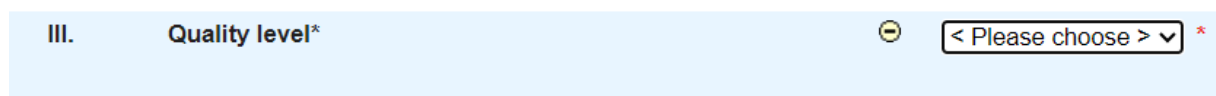
A checkbox is used for yes-no questions. In order to agree to the question, activate the checkbox with a mouse click. Clicking again removes the checkmark from the checkbox (Fig. 35).



**Diabetes mellitus\*\***   
**Arterial hypertension\*\***

Fig 35: Checkbox

Using selection lists, also called dropdown lists, you can select one of several answers from a list. First click on the arrow to open the list. Then click on the applicable answer in each case (Fig. 36).




III. **Quality level\***  \*

Fig. 36: Dropdown list

In the case of an expandable selection list, you have the possibility to add your own entries to a second list in case the given selection is not sufficient. This is done with the button OTHERS (Fig. 37). You will then get an additional input field, in which you can enter the new entry. By clicking the small triangle or when saving the form, this entry is then transferred to the second list next to it. You can also select an entry directly from this list. By clicking the SELECT button you will return to the first list. The first list contains all answer options given by the project design.

The second list contains all entries added by you or other users (Fig. 38). Hierarchical selection lists build on each other. The selection in the first list determines the selection options in the subsequent list.

**Diagnose:**    
**Andere**

*/Diagnosis/*

*/<Please select>/*

*Fig. 37: Selection list – Others*

*/Others/*

**Diagnose:**    

*/Diagnosis/*

*/Selection/*

*/<Please select>/*

*Fig. 38: Selection list – Selection*

## 5.2. Scores

Calculation fields (scores) show the result after clicking SCORE. If the form has already been saved, the saved value will already be displayed when you open it. Clicking on SCORE then performs a new calculation (with the current values).



All scores of a form can be calculated using the CALCULATE SCORES button below the form. The scores are also calculated automatically when the form is saved and are then also displayed on the print preview.

## 5.3. Repeating groups

By including subforms in repeating groups, you can make multiple entries for one item. An example would be the entry of all prescribed medications.

**Behandlungsphase 2**

*Behandlungsphase 2 1*

1.	<b>Startdatum</b>	<input type="text"/> - <input type="text"/> - <input type="text"/> dd.mm.yyyy  <input type="radio"/> unbekannt <input type="radio"/> nicht erhoben (*)
2.	<b>Enddatum</b>	<input type="text"/> - <input type="text"/> - <input type="text"/> dd.mm.yyyy  <input type="radio"/> unbekannt <input type="radio"/> nicht erhoben (*)
	<b>Ongoing</b>	<input type="radio"/> ja <input type="radio"/> nein *
3.	<b>Dosislevel</b>	<input type="radio"/> Level 1 <input type="radio"/> Level 2 <input type="radio"/> Andere *
4.	<b>Chargennummer</b>	<input type="text"/> *
	<b>Kit-Nummer</b>	<input type="text"/> *
4.1.	<b>Ausgabe der Studienmedikation gemäß Randomisierung?</b>	<input type="radio"/> ja <input type="radio"/> nein *

Delete  
More

Fig. 39: Repeating group

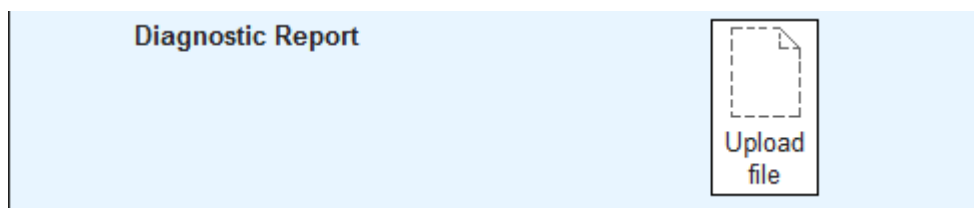
You can create a new group by clicking the CONTINUE button below or above the repeats. Create a new group or, if configured, delete a group by clicking the DELETE button (Alternative buttons are possible, e.g. a garbage can for deleting or a plus sign for adding).

The latter only if no queries or comments have been set in the group yet. Even the data of "deleted" repeating groups can still be viewed in the audit trail if they have been previously deleted, if they have been saved before. (Fig. 39).

#### 5.4. Uploading images

For uploading images, a link/button in the image component (Fig.40) opens a popup for file selection (Fig. 41). After starting the upload process, a progress bar is displayed in the popup and information about the processing status is displayed. In the main window, the form is hidden because no other operations can be performed during an upload.

If you close the popup or leave the form page, the upload is canceled. Canceling is also possible via a button in the popup. Then - or when the upload is finished the popup closes and the form is displayed again with the uploaded and scaled image. Only when the form is saved, the image is permanently referenced in the form. Otherwise it will be deleted from the server again.



*Fig. 40: Image item with link to upload popup*

### Import of form data

Please choose the form into which you want to import patient data.  
You can only import data to which you have sufficient access rights.

Project:

Centre:  all centres  Centre

Form:

Select an import format:

Visit plan:   
 repetition of this visit

---

Select the file for upload:

Fig. 41: Selection of the data to be uploaded

To download, the image in the display area or the original file name that is also displayed can be clicked. The download is then started via the browser and, depending on the browser settings the application corresponding to the file extension is opened for display. A download is also possible from the audit trail.

## 6. Form functions

In addition to the SAVE AND PRINT button and the CANCEL button for exiting the form without saving, there are also further functions described below. These are optionally available depending on the configuration of the project and on the role you are assigned to.

### 6.1. Entering and viewing comments and queries

The buttons to the right of the individual question in the forms activate special functions assigned to these questions or special functions assigned to these questions or question groups



### 6.1.1. Comments

Comments can contain remarks or notes, for yourself or for other Participants who have permission to access the corresponding patient data. If you have the authorization, you can enter comments on the individual forms, by clicking on the COMMENT button to the right of the relevant question in the form. If a question contains several items, you can choose between the individual items to which you want to place a comment. When you are finished with the input, save the comment with a click on SAVE. You can delete an unfinished entry by clicking CLOSE - without saving the comment first.

If you want to read all the comments on a form, click the COMMENTS button in the main menu at the top right of the page. Click CLOSE to return to the form, or PRINT to print the comments. In the form you will then see a question in which a comment has been made on an item will be marked with a small symbol [c] on the left side of the form. This icon can also be used to open the editing window for comments.

### 6.1.2. Queries

Queries are a tool for monitors and other authorized users to e.g. initiate follow-up examinations of unclear entries. If you want to read all queries of a form click on the QUERIES button in the main menu at the top right of the page. Also this function is only available after a form has been saved for the first time. Click CLOSE to return to the form, or on PRINT to print the queries.

To answer a query, click on the respective QUERY button and enter your answer in the input field. If a question contains more than one item, you can choose between the items for which you want to ask or answer a query. When you are done with the input, save your entry by clicking on SAVE. You can only save one entry for an item at a time per save operation. Click SAVE to save the entry or delete an unfinished entry by clicking CLOSE.

In the form, a question in which a query has been set on an item is then marked with a red symbol ("?" = open, "!" = answered or "v" = closed) on the left side of the form. Via this icon the query editing window can be opened, as well as via the menu at the top right of the form.

**Important:** If there are comments or queries to a question of a repeating group, this repeating group can no longer be deleted completely. In this case the button DELETE only deletes the data, not the group itself.

## 6.2. Question related help

An additional function on the forms is the question-related help, which, if available, is located right next to the comments and queries buttons. When you click on this HELP button, you will receive further information and instructions on the individual questions in a separate small window. Whenever you are unsure about how to answer a question, please check if a help text exists and provides clarity.

You can also print the help text. For this click the PRINT-button. Close the help-window via CLOSE-button.

## 6.3. Print

There are two methods to print a form. You can either use the PRINT-button in the main menu. It is located at the upper right of the page. You can also use the SAVE + PRINT-function at the end of each form. Note that the PRINT button only appears if the form has been saved at least once.

The PRINT button in the main menu at the top right prints the last saved (!) version of a form. A print preview will be displayed in a separate window, which you can close again after the printing process.

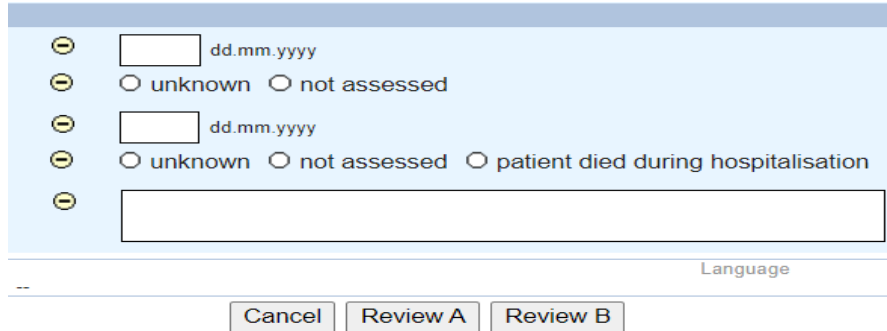
With the SAVE + PRINT button, the system will save all the new data you have added or changed to the form and then prints it. Here you will also see a print preview, which you can close again after the printing process. This process is noted as saving in the audit trail.

## 6.4. Review

SecuTrial® offers various options to support the typical study workflow of data management. This includes the possibility to lock patient data after completion of the data recording and subjected to various reviews in order to check the data and to close for further processing after the review. An initial review can be performed with the REVIEW A button for each individual form or for an entire visit. This review can be cancelled again with the REVIEW A button. A second review can be carried out with the REVIEW B button for each individual form or for the complete patient in this project (=all forms of all visits including the status forms of this patient in the current project). A review B can be cancelled by a query.

In each form there is a REVIEW-button next to the CANCEL-button on the form foot (labeled accordingly with „Review A“ or „Review B“). This button is for participants with review rights only and does not depend on the completion status. Exception: If a form contains a query that is not yet closed, the review B cannot be performed.

Pressing the REVIEW button locks the saved data status and makes further editing by a participant with write access (e.g. "Clinical Investigator") impossible. It can still set or cancel reviews, as well as edit queries and comments. Editing of the actual medical data is thus initially excluded.



The screenshot shows a form with a light blue header. It contains two date input fields, each followed by the text "dd.mm.yyyy". Below each date field are three radio button options: "unknown", "not assessed", and "patient died during hospitalisation". At the bottom of the form area, there is a "Language" label. Below the form, there are three buttons: "Cancel", "Review A", and "Review B".

*Fig. 42: Review A and Review B*

The corresponding form icon on the form overview gets a check mark on a green background and a side tab (below, if the review A has taken place; above, if the Review B has been done, where the two tabs complement each other). If in a form that has been subjected to a Review B, a query is placed by a participant, the form will be unlocked and lose its review-B status. It can only be closed again through a review B, in case the query has been answered (chapter 6.1.2. Queries).

When performing a review, any data changes made are not saved. If you have both the right to change data and to perform a review, you will be informed about this by a text below the buttons.

## 6.5. Source data Verification (SDV)








As a further step in data quality assurance, source data verification (SDV) can be configured for a project. This allows the comparison of study data with the original data in secuTrial® to be logged. The verification is basically possible for each item, but also randomly for forms, visits and the entire patient.

Each participant with the corresponding rights can perform a verification of the data after the verification of the available data. If a participant does not have the right to perform Source Data Verification, the SDV statuses are displayed, but cannot be changed.

There are five different SDV statuses (Fig. 43). If all items of a form have the same SDV status, this status is adopted as the status for the entire form and displayed in the form overview. If the items have different statuses, the form contains a symbol that marks this state. The procedure is analogous for form families, visits and the entire patient. When calculating the summed status of a form all items that are not displayed are not taken into account.

Each item has an SDV history. This is displayed in the popup window for changing the SDV status of an item. The collected SDV histories of all items of a form can also be called up via the button SDV-HISTORY in the form view. The history itself can be printed via PRINT and can be exited by CLOSING.

A change in the SDV states of the items of a form is noted in the audit trail of the form as "Source Data Verification".

SDV	Status	Description
	not done	No verification has been made on this item or form. (single or resulting status)
	in progress	Some items has yet not been verified or are deferred. So the verification is still in progress. (resulting status)
	deferred	A final verification is not possible at the moment. Perhaps a difference has been noticed which must be cleared. (single status)
	not possible	The original data has gone lost or a difference could not be cleared. So a verification could not be done. (single status)
	verified with errors	SDV has been made but for at least one item it was impossible. (resulting status)
	not necessary	A verification of this item or form is not necessary, e.g. when the SDV is only tested at random. (single or resulting status)
	verified	The verification has been finalized and there were no differences. The resulting status could include some items where the verification was not necessary. (single or resulting status)

*Fig. 43: Overview of all SDV status symbols*

## 6.6. Data entry complete (DEC)

If the DEC function has been configured for the project, when editing a form, you will get a new button SAVE + EXIT CAPTURE. You will get the new button only in case you have write access rights. By this kind of saving you declare the data acquisition for this form for completed and release it for further review. If the data entry should not to be completed, but the entered data must not be lost, you can use the SAVE button. For discarding the entered data without the CANCEL button is available for discarding the entered data without saving it (Fig. 44).

When DEC has been activated, the following functions for a form are only available after the end of the data collection:

- Source Data Verification
- Review A
- Review B
- Queries

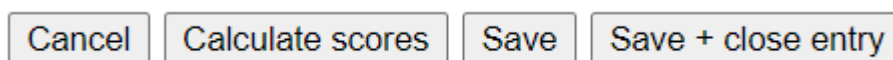
Once the data entry has been completed, no more data can be entered or changed in this form. Only after you have created a query for a specific question it becomes editable again, if you have the additional right EDIT INPUTS. All questions for which no query exists remain uneditable.

If data is to be changed after a DEC has been set and a subsequent query, you must specify a reason for the data change before saving. This reason is stored in the trail.

In the audit trail, the end of the data acquisition is marked with the note "Data acquisition completed", the subsequent data change is marked with "Data changed".

In order to enable a quick and easy data entry in case of an accidental click on the DEC button, there is the button OPEN CAPTURE. This function is only available as long as no review or block has been set on the form yet. In addition, no query must not have been set on the form or a status other than the SDV status "not performed".

The right to undo the DEC status is linked to the right to set the DEC status. If an e-signature is required to set the DEC status, it is also required to cancel the status.



*Fig. 44: DEC-Button*

## 7. Resources

The user manual is based on the manual provided for secuTrial® by the company iA Systems (Status: 02.03.2017).

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**DZHK**  
DEUTSCHES ZENTRUM FÜR  
HERZ-KREISLAUF-FORSCHUNG E.V.

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