



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

UNIVERSITÄTSMEDIZIN
GÖTTINGEN  **UMG**

secuTrial® - User Manual

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1. Introduction

This user manual is supposed to facilitate your use of the secuTrial® system's data entry tool (DataCapture). You can use DataCapture to capture, view and/or change medical data.

1.1. System Requirements

You may access secuTrial® DataCapture using various operating systems (such as Windows, MacOS, or Linux). You do not have to install any special software on your computer to be able to work with secuTrial® DataCapture. The software the tool required is installed on a central server. You can easily access it via any common browser (Microsoft Internet Explorer, Google Chrome, Mozilla Firefox, Safari etc.). We recommend the use of Mozilla Firefox or Microsoft Internet Explorer version 6.0 or later.

In your browser, you will need to enable JavaScript and SSL encryption as well as MetaRefresh (automatic redirecting). Java and ActiveX can be disabled. For security and data protection reasons, the cache should be cleared. If the browser provides any pop-up blocking, this must be disabled. If you need any support regarding browser settings, please contact your local system administrator.

1.2. General User Information

DataCapture is accessed via internet. A slow, unsecure, or unstable internet connection will inevitably lead to decreased system performance. The URL to be used (= internet address) for logging into DataCapture as well as your user identification (user name and password) have been sent to you via e-mail by the Data Handling task force of the University Medical Centre Goettingen. If not, please contact your study's chief investigator.

Depending on which browser you are using, window view, menu layout, or print layout might differ slightly. All DataCapture features have been tested under common browsers. Please remember to never use the browser features "Reload", "Back", "Forward" or the browser context menu, but only the secuTrial® navigation buttons (Figure 1).



Figure 1: Navigation buttons on the upper right

By clicking the CANCEL button (Figure 2), you will exit the current form without saving and will be redirected to the previous page.

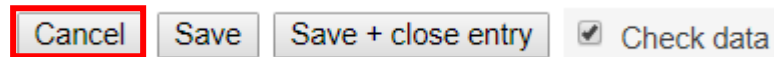


Figure 2: Cancel button

By clicking the LOGOUT button, you will exit the application. If you want to log in again, you will need to re-enter your user identification and password.

If there is no connection to the server for more than 60 minutes, you will be logged out automatically (“connection to the server” means: saving by clicking the SAVE button or changing form pages, but not the mere entering of data into a form). This will ensure that no unauthorised individuals might gain database access or change your data records.

The time remaining until logout will be displayed in the browser window’s title bar. If you are logged out automatically, data you have not saved before will be lost. If you pause working, you should save the form you are working on (using the SAVE button) (Figure 2).

Most pages in DataCapture have a help function which you can open by clicking on the HELP button in the main menu at the top right of the screen. For orientation, the header of all secuTrial® pages will constantly display the current user data.

2. Login

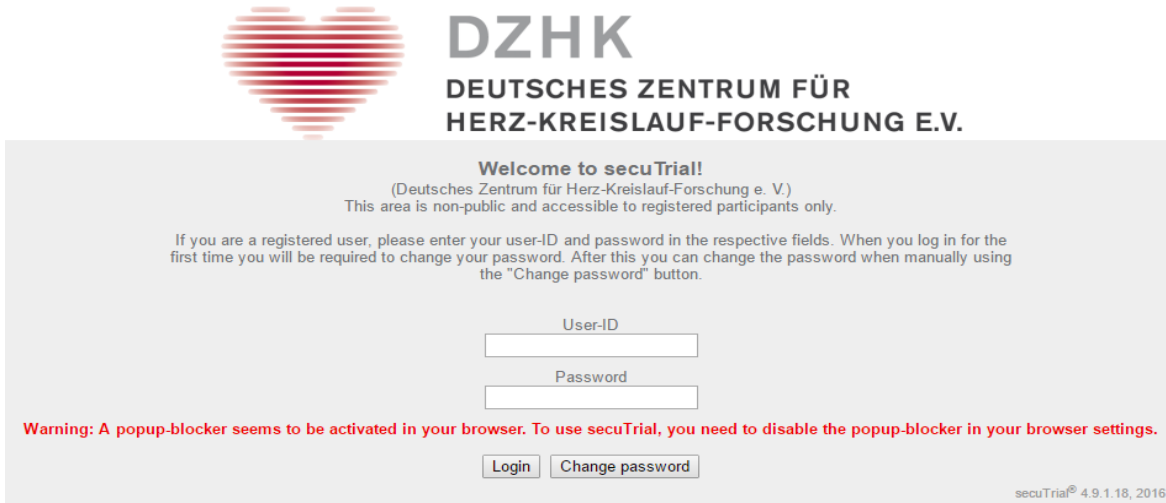


Figure 3: Login mask

For your first DataCapture login, please access the URL send to you by the Data Handling (from now on: DH) task force. In order to login, you will need user identification, consisting of user name (user ID) and password, which were provided by the DH as well. Under “User-ID”, please enter your user identification exactly as it has been assigned to you (Figure 3).

At first login, you will be required to change the password sent to you. Please enter a password of your own choosing and do not share it with anyone else. For security reasons, your password must comply with specific criteria:

- use at least 8 characters
- use lower and upper case letters as well as numbers
- use at least one special character (e.g.: ? ! % + \$! ? #).
- the new password must not be identical to the one sent to you.

You will be asked regularly to change your password (project setting). The new password must not be identical to the previous password.

Important: Please note that even though you already received a User ID and a password for the test system, you can’t use these to add patients into the productive system. DH will provide you with an additional identification.

2.1. Logout

Whenever you used your workstation and whenever you leave it, you must log out manually (LOGOUT in the upper menu bar) in order to prevent unauthorised individuals from using your account. After logout, you will see an information page. It will provide a link that will redirect you to the LOGIN page.



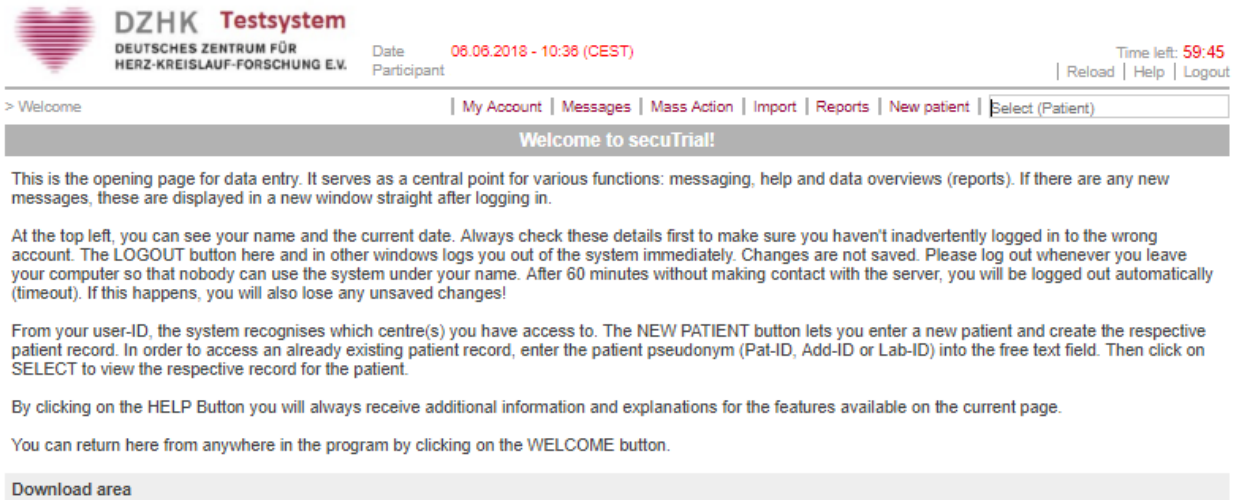
2.2. Changing Password

You can change your password at any time by clicking the MY ACCOUNT button on the LOGIN page. Just enter your previous password and provide a valid new password twice.

2.3. Forgotten Password

If you have forgotten your password, please contact the DH in Goettingen. They will send you a new password via e-mail afterwards. As your request will be processed manually, this might take up to one working day.

3. Welcome Page



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 '06.06.2018 - 10:38 (CEST)' and 'Time left: 59:45'. Below this is a navigation bar with links: 'My Account', 'Messages', 'Mass Action', 'Import', 'Reports', 'New patient', and 'Select (Patient)'. The main content area is titled 'Welcome to secuTrial!' and contains several paragraphs of text providing instructions and information about the system. At the bottom, there is a 'Download area' section.

Figure 4: "Welcome" page view

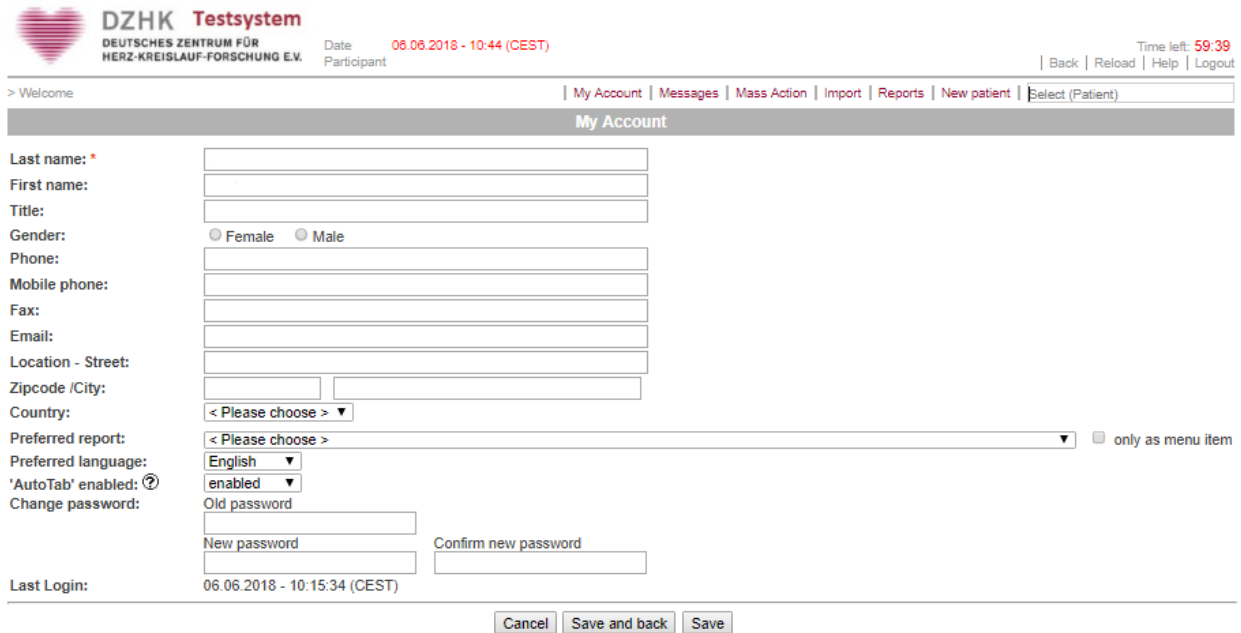
The WELCOME page is the central access point for the individual secuTrial® features (Figure 4). Depending on the role assigned to you and the configuration, you can:

- Access and change your preferred language (MY ACCOUNT)
- Create a new patient (NEW PATIENT)
- Access patient information/Entering and Editing Data (SELECT)
- Access reports and statistics (REPORTS)
- View and write messages (MESSAGES)
- Import form data or discrepancies (IMPORT)
- Download documents (under DOWNLOAD AREA)

The WELCOME page contains general information regarding the use of the application. By using the HELP button, you can open more detailed descriptions for each individual feature. You can return to this starting point via the WELCOME button available on each DataCapture page.

3.1. My account

By using the MY ACCOUNT button, you can set up a preferred language for DataCapture (Figure 5). Currently, German and English are available. If you do not make a choice, the default setting of the project or of the current client will be used.



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

Date: 06.06.2018 - 10:44 (CEST)
Participant

Time left: 59:39
| Back | Reload | Help | Logout

> Welcome | My Account | Messages | Mass Action | 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: < Please choose >
Preferred report: < Please choose > only as menu item
Preferred language: English
'AutoTab' enabled: enabled
Change password: Old password, New password, Confirm new password
Last Login: 06.06.2018 - 10:15:34 (CEST)

Cancel Save and back Save

Figure 5: "My Account" page view

3.2. Adding a new patient to the database

A client certificate from the DZHK trustee is required for you to be able to create a new patient within the secuTrial® system. The certificate can be requested using a separate form that is part of the IT file and has been provided to your chief investigator. This form must be filled in and sent to the trustee in Greifswald. You will receive a client certificate afterwards to be imported into your browser. When finished, you can create a new patient as follows:

1. After logging in, click the NEW PATIENT button on the upper right of the WELCOME page (Figure 6).



Figure 6: Menu "Welcome" page

2. Enter the entry date into the upcoming date field and click CONTINUE (Figure 7).

Figure 7: Creating a new patient

3. Select the certificate issued by the trustee and click OK. For further information on who to capture a new patient, please read DZHK-SOP-TTP-01: Acquisition of person identifying data and the informed consent at the DZHK website for study preparation and study management.
4. Now the patient has been created in secuTrial® under the pseudonym displayed. Click CONTINUE to go to the visit plan (Figure 8).

Figure 8: Patient has been created

5. Within the visit plan (Figure 9), you can open the individual forms for entering data by clicking. Always complete the data-entry process via SAVE, as the data you entered will not be saved otherwise.

Planned visits	Baseline Visite	Next visit
Data entry	05.06.16	
Anamnesis and Clinical Diagnoses (incl. Basic Data Set**)	[Icon]	[Icon]
Cardiomyopathy Diagnostics	[Icon]	[Icon]
ECG	[Icon]	[Icon]

Figure 9: Example visit plan

3.3. Access patient information/Entering and Editing Data

There are two ways to call up a patient already created.

1. Enter the patient's pseudonym on the upper right of the WELCOME page under SELECT (Figure 10).

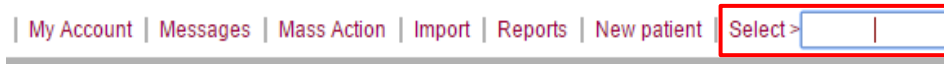


Figure 10: How to call up a patient - SELECT

2. Click the REPORTS button on the upper right of the WELCOME page (Figure 11). Now you can display a list of all previously created patients for your site (Figure 12). By clicking the pseudonym of an individual patient, you can open the visit plan (form overview) and enter data there.



Figure 11: How to call up a patient - REPORTS

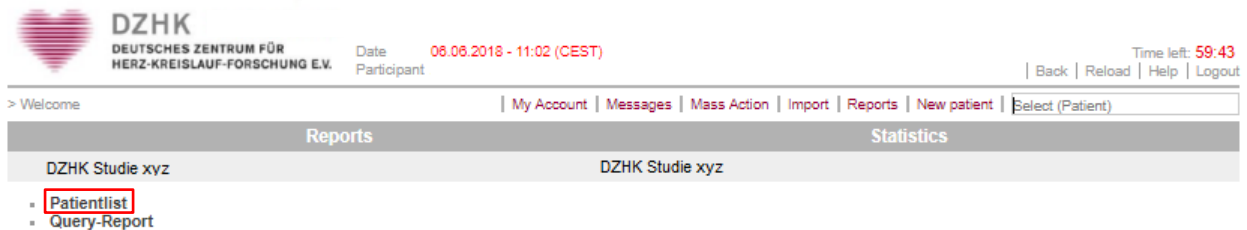


Figure 12: "Reports" page view

The visit plan is the central starting point for entering or editing data (Figure 13). The icons provide a quick overview of the status (see chapter 3.5 Status and Help) of the various forms and form groups (form family).

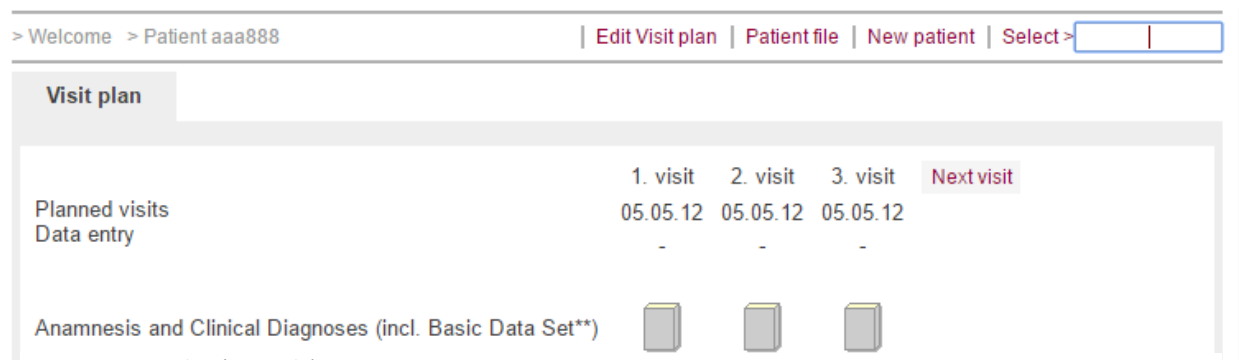


Figure 13: Visit plan (example)

One form family may contain one or several forms. If a form family only contains one form, that one will open directly after you clicked the form family icon. If a form family contains several forms, an overview of the forms will be displayed first in the page's footer (Figure 14). Clicking the form family icon again will close it. Individual forms can also be opened by clicking the corresponding icon at the bottom. The individual forms usually can be opened and edited in any order.

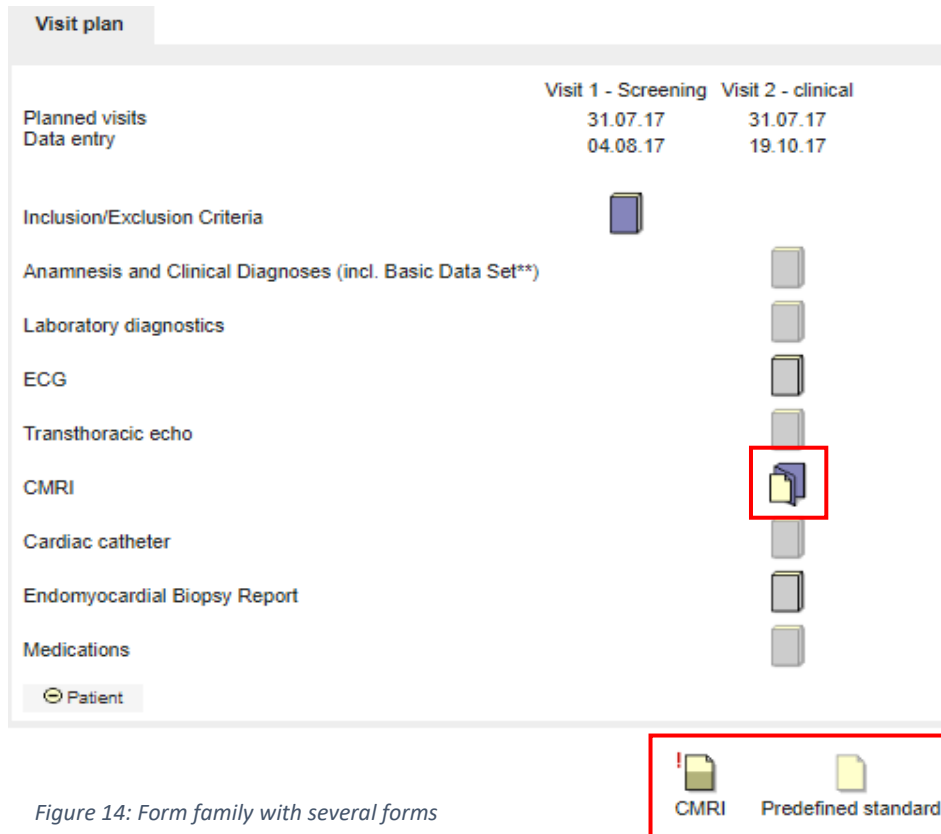


Figure 14: Form family with several forms

You can use the HELP button within the form overview to call up an overview of the icons and their meaning (see chapter 3.3.3 Status and Help). The form overview header (Figure 15) will display project, date, site, and pseudonym of the called-up patient. The main menu on the upper right of the page contains navigation buttons allowing you to return to the WELCOME page (WELCOME) or to log out of the system (LOGOUT).



Figure 15: Formular Header

3.3.1. Creating Next Visit

If you want to enter data for a next visit, click the NEXT VISIT link (Figure 16). If different visit types (scheduled and unscheduled) are specified for the current project in the visit plan template, you can now select a type. For unscheduled visits, you will have to indicate the date of the next visit (Figure 17).

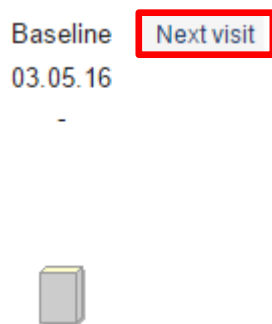


Figure 16: Next visit link

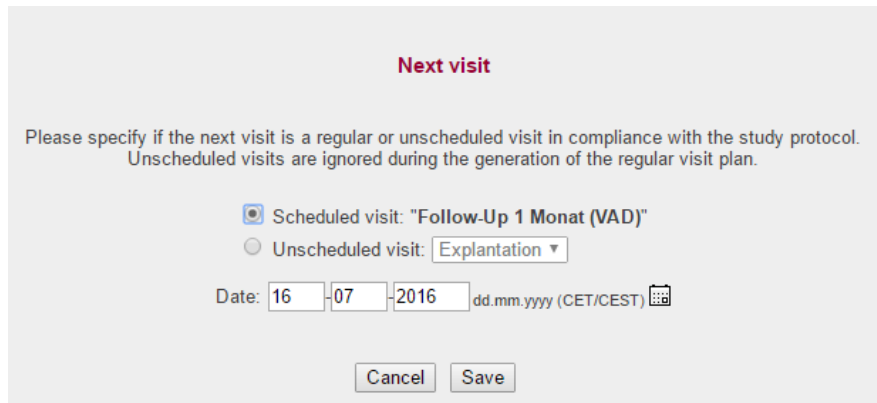


Figure 17: Entry field for visit type and date of the next visit

Depending on the settings for the study, you also might be able to create visits in non-chronological order. The internal visit numbering will match the order of creation. The view within the form overview will remain in strict chronological order, i.e. sorted by visit date. A new form record will be provided for each new visit and can be opened by using the corresponding icons.

3.3.2. Changing an Existing Visit

If you entered the wrong visit date by mistake, you can change it under the provision that no data have been saved in the visit to be edited and any subsequent visits yet. This means that for a series of visits without data, each visit may be edited as long as the configuration for the previous visit allows for this. Therefore, for sequential fixed visits, only the entry date can be edited. Subsequent visits will be rescheduled according to the changes made to the first adjusted visit.

If you want to change visit date and type, please click the EDIT VISIT PLAN link (labelling might differ depending on configuration) (Figure 18).



Figure 18: Editing a visit plan

If you change the visit of an unscheduled visit, internal numbering of the changed visits and any other unscheduled visits will be adjusted. After a date or a visit has been changed, the new visit plan will be calculated, checked against the project visit plan, and errors will be displayed, if applicable. You can only save visit plans that match the configuration (Figure 19).

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.

move subsequent visits accordingly
 only edit individual visits
 adjust numbering of unplanned visits

Entry date	05.05.2012 (CEST)	<input type="text" value="05"/>	<input type="text" value="05"/>	<input type="text" value="2012"/>	dd.mm.yyyy (CET/CEST)
1. visit	05.05.2012 (CEST)	<input type="text" value="05"/>	<input type="text" value="05"/>	<input type="text" value="2012"/>	dd.mm.yyyy (CET/CEST)
2. visit	05.05.2012 (CEST)	<input type="text" value="05"/>	<input type="text" value="05"/>	<input type="text" value="2012"/>	dd.mm.yyyy (CET/CEST)
3. visit	05.05.2012 (CEST)	<input type="text" value="05"/>	<input type="text" value="05"/>	<input type="text" value="2012"/>	dd.mm.yyyy (CET/CEST) Delete

Figure 19: Page for editing a visit plan

When changing a visit plan, you must provide a reason when saving. The reason will be displayed in the visit plan history to allow for tracing back changes at a later time.

3.3.4. Status and Help

The status of the forms (empty, partially filled, or completely filled) is indicated by different colouring of the icons of the visit plan forms. You can use the HELP button on the form overview page to open a window displaying the page "HELP – FORM OVERVIEW." You will see the meaning of the icons there (Figure 20).

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.
	data entry complete	The data entry is finished. This status does not display the underlying completion status.
Symbol	Status	Description
	validation	The rule validation of this form finished with problems (warning, error).
	comment	At least one comment has been posted.

Reload Help Logout
 Select >

Figure 20: "Help" window with explanation of form icons



3.3.4. Project Selection

If a patient has been enrolled into several projects or studies, you can switch between the separate (sub-) projects, provided you have been authorised to view these studies. Use the selection list at the right side (within the border surrounding the form icons). The list will only be displayed if the patient is enrolled in several sub-projects and if you have corresponding access to or authorisations for these projects.

3.4. Reports and statistics

If you click on the REPORT button in the main menu, you will obtain an overview of all of the reports and statistics created for your project which your rights permit you to view. The preferred report that has been defined for the participant (editable in My Account – Preferred Report) will be displayed as an additional menu button on the Welcome page, Form Overview page and Form page (see chapter 3.1- My account). If you click on this button, the preferred report will open in an additional pop-up window. Directly after logging in, your preferred report will immediately open in a pop-up window. If you only wish the report to appear as a menu item option, you can configure this accordingly in My Account.

3.4.1. Reports

After selecting a report by clicking on its title, it will open in a new window together with an overview of all the patients (or results) for your assigned centres. One entry (line) is usually displayed for each patient included in this report. Reports are always displayed in a separate report window which is independent from all other windows. The report window remains open even if an additional window is opened in the form view, e.g. to edit queries. All reports are always opened in the same window.

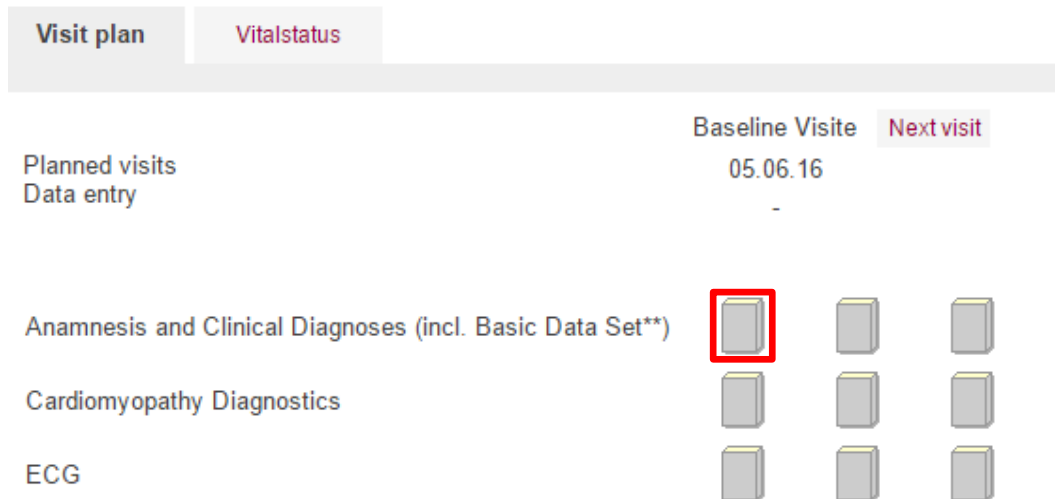
If a help text has been defined for a report in the FormBuilder the menu of the report window in DataCapture will include a help button. This button opens an additional, small pop-up with the defined help text.

3.4.2. Statistics

After selecting an individual statistic it will open in a separate window and the number of patients with a defined data criteria will be graphically displayed. These are summaries of patient data and do not show individual patients. After viewing, statistics can be printed with the PRINT button. To close the window, click on the CLOSE button. The data can be exported to Excel by clicking on the EXCEL button.

4. Entering patient data

By clicking the corresponding icon of the form or form family within the form overview, you can open the form you want to edit (Figure 21).







	Baseline Visite	Next visit
Planned visits	05.06.16	
Data entry	-	
Anamnesis and Clinical Diagnoses (incl. Basic Data Set**)		
Cardiomyopathy Diagnostics		
ECG		

Figure 21: Visit plan

Once a form has been filled in, it is mandatory that you click SAVE for the data to be sent to the secuTrial® database. Otherwise, the data captured so far will not be saved. When editing larger forms, it is recommended to save the captured data regularly to avoid any loss of data due to any timeouts. If you have entered data correctly and saved the form, you will receive a confirmation accordingly. Underneath the form you will see author, date, reason, and, if applicable, validity of the signature from the most recent saving process. On the confirmation page, you can decide if you want to go right to the next form, back to the current form, or back to the form overview.

Notes

- Navigation buttons (WELCOME, HELP, LOGOUT, etc.) will be displayed within the main menu on the upper right.
- Additional buttons PRINT, QUERIES, COMMENTS refer to the opened form.
- PRINT can be used to print the current form's version that has been saved to the database most recently (!).
- The buttons QUERIES and COMMENTS can be used to view queries and comments for the current form, provided the corresponding authorisation has been granted.
- At the bottom of the page, further buttons are available: CANCEL will exit the form without saving changes to the medical data. SAVE will save the data entered into the form to the secuTrial® database.



- You will not have to directly fill in a form completely every time. It is possible to enter data and save partial information provisionally, i.e. you can continue with data capturing at a later time. The fields requiring an entry are marked (see below) or show a corresponding note when saving.
- Some Items may be marked with red asterisk* (Figure 22). Items marked like this are mandatory. The form can't be saved as long as these fields aren't filled in. In some cases items are marked with one* or two black asterisks** (Figure 22 and 23). Those are items that can't be changed due to DZHK harmonisation procedures.
- If another participant has already opened the form, it will be locked and no data can be entered into it. A note will be displayed in such a case (Figure 24).

1.4. Weight**	<input type="text"/> kg*	<input type="radio"/> estimated <input type="radio"/> measured *
1.5. Height**	<input type="text"/> cm*	<input type="radio"/> estimated <input type="radio"/> measured *

Figure 22: Items marked as mandatory

2.6. Drinks per week*	<input type="text"/>	<input type="radio"/> unknown <input type="radio"/> not assessed
------------------------------	----------------------	--

Figure 23: DZHK harmonized items

secuTrial®

Date	14.06.2018 - 08:25 (CEST)	Patient	Pat-ID imq680	Time left: 59:44
Formular Builder		Screening	23.06.2017	
Project		Form family	In/Exclusion Criteria	
Centre		Form	In/Exclusion Criteria	Back Reload Help Logout

> Welcome > Patient imq680 > In/Exclusion Criteria

This patient is currently locked by another user, therefore editing is impossible.

In/Exclusion Criteria

1. Informed consent

1.1. ICF signed by subject and investigator	<input type="radio"/> yes <input type="radio"/> no	Comment
1.2. Date when ICF was signed	<input type="text"/> dd.mm.yyyy hh:mm	

Figure 24: Error message

Important: Please note that that the data are only saved if the notice below appears! You can decide how to continue e.g. back to form or edit the next form (Figure 25).

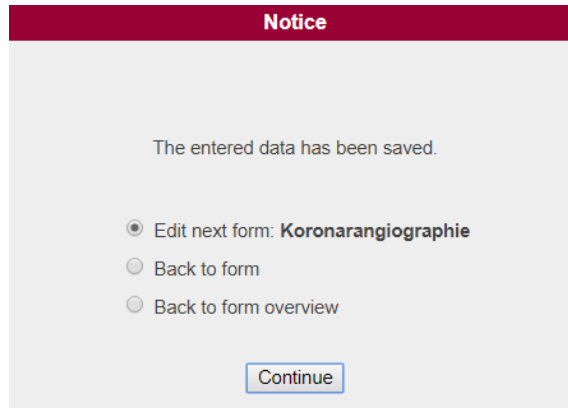


Figure 25: Notice

4.1. Plausibility check

Various data checks have been integrated to minimize the risk of entering erroneous data into secuTrial® DataCapture and thus to increase data quality. These checks will notify you of any potentially erroneous data when you are trying to save a form. By default, data formats (e.g. “30 February” is not an allowed date), logical plausibility (e.g. male patients cannot be pregnant), and value limits (e.g. a heart rate > 250 is unlikely) will be checked.

If there are any data issues that cannot be resolved during data capture, but you still want to continue capturing data, you can disable the plausibility check. To do that, you will need to disable the CHECK DATA checkbox next to the SAVE button. Next, click SAVE. However, in order not to jeopardize data quality, disabling must not become a rule but should always remain an exception. It can also be of use for large forms, for cases where you need to pause data capture but cannot save the form in its current state yet due to prevention by a regular check.

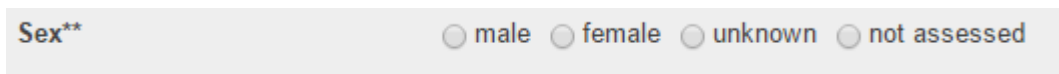
As a basic principle, erroneous formats (e.g. letters within number fields) cannot be saved. Error messages overridden this way will have a red exclamation mark next to the form icon.

4.2. Summary: Data capture steps within forms

1. On the form overview, click the icon of the form you want to edit.
2. Enter the data in the specified fields.
3. Save the entries using SAVE.
4. Data entry will be confirmed. You can now decide whether you want to edit the next form or want to return to the form overview.

4.3. How to handle missing values

The secuTrial® database forms contain different types of questions or different form components (see chapter 4). For either-or questions (radio button), you will also be able to answer UNKNOWN and NOT ASSESSED. The option UNKNOWN indicates that the value is not known (Figure 22). For example, cardiopulmonary exercise testing has been performed, but the date of conduct is not known, wherefore the date would be “unknown”. The option NOT ASSESSED indicates that a value has not been recorded because of the question not being applicable. For example, a patient did not have any cardiopulmonary exercise testing, wherefore no examination date has been recorded.



Sex** male female unknown not assessed

Figure 26: Radio button with UNKNOWN and NOT ASSESSED options

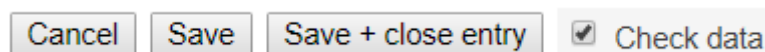
If the form component to be filled in is not an either-or question, but e.g. a date field, the answer options UNKNOWN and NOT ASSESSED will not be displayed right next to the entry field. Instead, the entry field will have a circle with a check mark (Figure 23). Clicking on this icon will open a new window. In that window, you can indicate whether the value is unknown or has not been recorded (missing value).



Date of birth** - mm.yyyy 

Figure 27: Date field with MISSING VALUE

If e.g. for a date field, you neither enter the date nor indicate a missing value, you will receive an error message when trying to save the form. If you still want to save the form although you did neither enter the date nor indicate a missing value, you can disable the CHECK DATA checkbox at the bottom of the currently opened form (Figure 24). You can do this by clicking the check mark in the box next to “Check data.” The check mark will disappear and the checkbox will be disabled. As a result, all missing values as well as all other rules of the form will not be checked when you save the form.



Check data

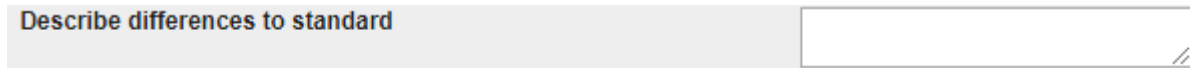
Figure 28: CHECK DATA

5. Form Components

Entering data into the forms is done via various types of questions. You should be familiar with the use of most elements from filling in internet forms. However, secuTrial® provides some combined fields that offer additional functionalities.

5.1. Basic Form Components

You can enter any text into **text fields**. Text length is limited to the length implemented in the setup (Figure 25).



A screenshot of a form component showing a text input field. The label "Describe differences to standard" is positioned to the left of the input box. The input box is empty and has a small cursor icon at the bottom right corner.

Figure 29: Text Field

Number and date fields are limited to entering numbers only, i.e. valid dates or times (Figure 26). Some date fields must be filled in completely, whereas for others, sub-information (e.g. the day) can be omitted. The required format will be displayed to the right of the field. Decimal places are entered via a second number field (Figure 27).



A screenshot of a form component showing a date input field. The label "1.1. Date obtained" is positioned to the left of the input box. The input box is divided into three sections for day, month, and year, with a calendar icon and a red asterisk to the right. The format "dd.mm.yyyy" is displayed to the right of the input box.

Figure 30: Date field with the required format and calendar

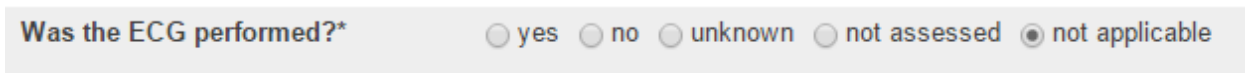


A screenshot of a form component showing two number input fields. The first field is labeled "Platelets*" and the second field is labeled "Na". The second field has a decimal point and a unit "mmol/l" to its right.

Figure 31: Number fields with measuring unit

For either-or questions, a **radio button** is used, allowing only one answer. Using a reset radio button, you can reset your answer via NOT APPLICABLE (Figure 28).

Important: If the radio button has no reset option (as at the DZHK), you can undo your selection by double-clicking the "checked" answer.



A screenshot of a form component showing a radio button question. The label "Was the ECG performed?*" is positioned to the left of the radio buttons. The options are "yes", "no", "unknown", "not assessed", and "not applicable". The "not applicable" option is selected, indicated by a filled radio button.

Figure 32: Resettable radio button

For yes-no questions, a checkbox is used. A mouse click on the checkbox will answer the question with “Yes”. Clicking again will delete the check mark (Figure 29).



Figure 33: CHECKBOX

Selection lists (dropdown lists) allow you to select a pre-set answer from a list (first list). First click the arrow to open the list and select the relevant answer next (Figure 30).

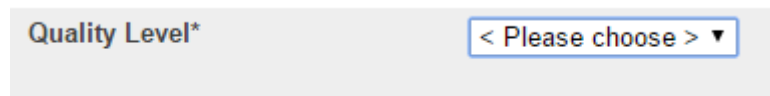


Figure 34: Dropdown list

Extendable selection lists allow you to add your own entries into a second list for cases where the selection does not apply and the list requires additional answer options. The first list contains all answer options pre-set by project design, the second list will contain all entries added at a later time by yourself or other users. Additions can be made using the “OTHER” button (Figure 31). An additional entry field will display for the new entry to be inserted. Clicking the small triangle or saving the form will add this entry to the second list. You can also select an entry already added by another user or yourself at a previous time directly from this list. Clicking the “SELECTION” button will take you back to the first list (Figure 32). Hierarchical selection lists are based on one another. The selection made in the first list will define the choices available in the sub-list.

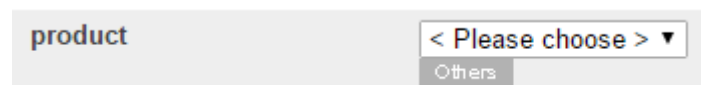


Figure 35: Selection lists - OTHERS



Figure 36: Selection list - SELECTION

5.2. Scores

Calculation fields (scores) will display the result after clicking SCORE. The score is calculated automatically from already captured data, using a defined calculation rule/formula. If the form has already been saved, the recently saved value will be displayed on opening the form. Repeated clicking on SCORE will trigger re-calculation (using current values).

All scores of a form can be generated by using the “CALCULATE SCORES” button underneath the form, or automatically when saving. They will appear in the print view afterwards.

5.3. Repetition Groups

By embedding sub-forms into repetition groups, you can provide multiple information for one item thanks to the possibility of repeating a question or group of questions as often as required. For example, you could capture all prescribed medicinal products.

4.19. Please complete form in the order of stent placement (i.e. first stent implanted first)

Stent placed 1

Coronary Segment *

FFR . *

(e.g. 0.75)

Type of stent BMS DES *

Stent length . mm*

Stent diam. . mm*

Post stenosis . %*

FFR (post) . *

(e.g. 0.75)

Comments

Stent placed 2

Coronary Segment *

FFR . *

(e.g. 0.75)

Type of stent BMS DES *

Stent length . mm*

Stent diam. . mm*

Post stenosis . %*

FFR (post) . *

(e.g. 0.75)

Comments

Figure 37: Example repetition group

By clicking the MORE button, you can create a new repetition group, or you can delete a group using the DELETE button, if configured. The latter is possible only if there are no queries or comments for any of the questions of that repetition group yet (Figure 33).

5.4. Uploading Images

To upload images, click on the link/button in the image component to open a pop-up window for selecting a file (Figure 34). After starting the upload process, a progress bar and the processing status will appear in the pop-up window (Figure 35). The form will be hidden in the main window, as no further procedures may be carried out while uploading. If you close the pop-up window or leave the form page, the upload will be cancelled. You can also cancel by clicking on cancel in the pop-up window. After cancelling or after the upload has been completed, close the pop-up window and the form will be displayed again with the uploaded and scaled image. Only after the form has been saved will the image be permanently referenced in the form, otherwise it will be deleted from the server.



Figure 38: Image item with a link to the upload pop-up window

Image upload

Upload an image file

Please choose a file to upload:

 Or open the Dicom file chooser: [Dicom-Browser](#)

(The upload can take quite some time depending on the file size and connection.)

Figure 39: Upload image: selecting the file to be uploaded

Images can be downloaded from the display window or by clicking on the original file name. Downloading will begin in your browser and the file will be opened with the application specified in your browser for this file type. Downloading is also possible from the Audit Trail.

6. Form Functions

Apart from the SAVE AND PRINT button and the CANCEL button used for exiting the form without saving, forms will have the features described below, which will appear optionally depending on project configuration and the role assigned to you.

6.1. Entering and viewing comments and queries

The buttons right of the individual questions in the forms will enable the special features assigned to the questions or groups of questions. COMMENTS and QUERIES can be used to view associated comments and queries.

6.1.1. Comments

Comments may contain remarks or instructions for yourself or other participants who have permission to access the patient in question. If you have the required authorisation, you can enter comments into the individual forms by clicking on the COMMENT button to the right of the respective question. If a question contains several items, you can select which of the individual items you wish to comment on. When have finished making a comment and wish to save it, click on SAVE. You can delete incomplete entries if you have not saved them by clicking on CANCEL.

To read all of the comments in a form, click on the COMMENTS button in the main menu at the top right of the page. Click on CANCEL to return to the form or PRINT to print the comments.

In the form, a question in which a comment has been created in relation to an item is indicated with a small, red symbol "c" on the left edge of the form. Via this symbol the editing window for comments can be opened, just like via the menu on the right-hand edge of the form.

6.1.2. Queries

Queries are supposed to help monitors and other authorised users, so they may e.g. initiate editing of unclear entries. If you want to read all queries of a form, click the QUERIES button in the main menu on the upper right of the page. This feature will not be available until queries have been saved in a form. Click CLOSE to return to the form, or click PRINT to print queries.

To answer a query, click on the respective QUERY button and enter your answer in the input field. If a question contains several items, you can choose an individual item to query or create an answer. When have finished your entry, click on SAVE to save your entry. It is only ever possible to save one entry per item at a time. To delete an unfinished entry click on CANCEL.



In the form, a question in which a query has been created in relation to an item is indicated with a small, red symbol ("?" = open, "!" = answered or "v" = closed) on the left edge of the form. Via this symbol the editing window for queries can be opened, just like via the menu on the right-hand edge of the form.

Important: If there are any comments or queries concerning questions of a repetition group, deleting this group completely is no longer possible. In such a case, the DELETE button underneath the group (if available) will only delete the data, not the group itself.

6.2. Question-Related Help

An additional function provided in the forms is the question-based help function. If available, this is located to the right of the questions for the comments and queries buttons. Click on the HELP button to obtain information and instructions on the individual questions in a separate window. If you are uncertain as to how a question should be answered, check to see whether a help text is available to provide clarification.

The help texts can also be printed out by clicking on the PRINT button. To close the help window, click on the CANCEL button.

6.3. Print

There are two methods to print a form. You can either use the PRINT button in the main menu (on the upper right of the page) or the SAVE AND PRINT function at the bottom of the individual forms (the second option is not enabled at the DZHK). Please be aware that the PRINT button in the main menu will only appear if the form has been saved at least once.

The PRINT button in the main menu at the top right of the page prints the version of the form which was last saved! A print preview is displayed in a separate window, which you should then close after printing.

By pressing the SAVE + PRINT button, all data which has been added to the form or changed will be saved and then printed. A print preview will be displayed, which you should close after printing. In the Audit Trail this action will be recorded as a save procedure.

6.4. Review

secuTrial® offers various ways to support the data management work flow which is typical in medical studies. This includes locking patient data after data entry has been completed and enabling various reviews to check the data before releasing it for further processing.

The first review can be performed with the REVIEW A button for each individual form or for an entire visit. The review can be revoked with the REVOKE REVIEW A button. A second review can be performed with the REVIEW B button for each individual form or for all of the patients within a project (i.e. all forms from all visits, including the status form of the patient in the current project). A review B can be revoked through a query.

Regardless of the form completion status, participants with a review rights will find a REVIEW button (marked “Review A” or “Review B”) next to the CANCEL button at the bottom of every form. Exception: if the form contains a query that has not yet been closed, a Review B cannot be performed.

Clicking on the REVIEW button locks the saved data and prevents further editing by participants with writing rights (i.e. Clinical Investigator). It is still possible to write and revoke reviews and to edit comments or queries. Editing the actual medical data, however, is not possible for the time being. After a review has been completed, the form icon in the form overview will be displayed with a triangular flag beside it (a flag at the bottom once a Review A has been performed, a flag at the top once a Review B has been performed). If a form has undergone a Review B and a query is then created by a participant, the form will be locked and will lose its Review B status. The form can only be closed with a Review B once the query has been answered (see chapter 6.1.2).

When performing a review, any data changes that are made will not be saved. If you have the right to both change data and conduct a review, you will be reminded of this accordingly in a notification underneath the buttons. The final locking of a form is performed using the FREEZE button for each individual form, for each visit on the form overview page or for the entire patient (=all forms of all visits including the status forms of the patient in the actual project) as well on the form overview page (here: FREEZE PATIENT) (Figure 36). Afterwards it is no longer possible to perform reviews and/or create queries.

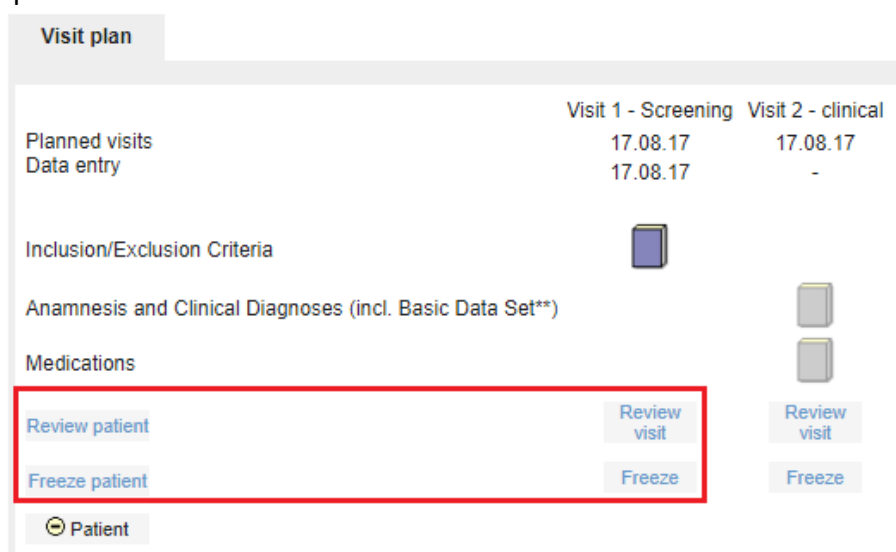


Figure 40: Visit plan with the buttons for reviewing or freezing all forms of one visit (right) for reviewing or freezing all of a patient's forms (left)

6.5. Source Data Verification (SDV)

Source Data Verification (SDV) is an additional process which can be configured for a project to ensure data quality. It enables comparisons between the study data and the original data to be recorded in secuTrial®. Verification is possible for every item, however summary checks or random spot checks are also possible for forms, visits and all patients.

After data entry has been completed, participants with the respective rights can perform a verification of the existing data. If the participant does not have the rights to perform a Source Data Verification, the SDV status will be displayed but cannot be changed.

There are five different types of SDV Status. If all items in a form have the same SDV status, this status will be adopted for the entire form and displayed in the form overview. If the items each have a different status, the form will be given a symbol to reflect this. The same procedure applies for form families, visits and the whole patient. When calculating the summarised status of a form, all hidden items will no longer be taken into account.

Click on the HELP button in the form overview for explanations of the various SDV symbols (Figure 37). Every item has an SDV history. This is displayed in the pop-up window for changing an item's SDV status. The SDV history of all items within a form can also be accessed via the SDV HISTORY button in the form view. Click on PRINT to print the history or CLOSE to leave the window.

Changing the SDV status of the items in a form is recorded as "Source Data Verification" in the Audit Trail.








SDV	Status	Beschreibung
	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)

Figure 41: Overview of all SDV status symbols

6.6. Data Entry Complete (DEC)

If the DEC function has been configured for the project and you have the necessary writing rights, you will see a SAVE + CLOSE ENTRY button when editing forms. Use this saving procedure to declare data entry to be complete for this form and to release it for further checking. If the data entries have not been completed but the entered data needs to be saved, use the SAVE button. If none of the entered data is to be saved, click on the CANCEL button (Figure 38).

When DEC is activated the following form functions will only be available after the data entry has been completed:

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

As soon as the data entry in a form has been completed, no further data entries or changes are permitted in this form. Only after a query has been created regarding a particular question is it possible for the form to be edited by a participant with the additional right to MODIFY ENTRIES. Questions without any queries will remain unavailable for editing.

If data needs to be changed after a DEC has been set and a query has been created, when saving the form a reason must be given for changing the data. This will be saved in the Audit Trail.

In the Audit Trail, data entry completion is recorded as “Data entry completed” and subsequent data changes as “Data modified”. Should you accidentally click on the DEC button, click on REOPEN ENTRY to quickly and easily re-enter the data. This function can only be used as long as no review has been conducted and provided the form has not been locked. Furthermore, there must not be any open queries or any other type of “not done” SDV status.

The right to revoke the DEC status is linked with the right to set a DEC status. If an e-signature is required for setting the DEC status, it will also be required for revoking it.

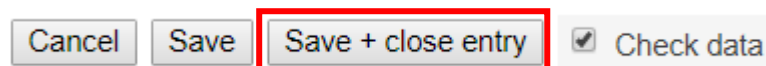


Figure 42: DEC-Button



7. Resources

The user manual is based on the patient manual provided for secuTrial® by company iA Systems (as of: 19 July 2017).



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