

# secuTrial® 4.9.0.8

Released 12/05/2015

based on Version 4.8.0.19



## Introduction

This version introduces a series of functions that will simplify general management processes in the AdminTool as well as data entry in DataCapture.

The following new functions have been added:

- |     |                   |   |         |
|-----|-------------------|---|---------|
| 1.  | All tools         | User-friendliness   | Page 2  |
|     |                   | <ul style="list-style-type: none"> <li>– Automatic password reset for participants (c)</li> <li>– Remaining session time displayed on the page</li> <li>– Error pages</li> <li>– Auto-tab option and calendar in all date fields</li> <li>– Multiple attempts at sending an e-mail</li> </ul> |         |
| 2.  | CustomerAdminTool | Display update history and configuration  | Page 5  |
| 3.  | CustomerAdminTool | Configuration of automatic sending of passwords for participants  | Page 6  |
| 4.  | CustomerAdminTool | Event log   | Page 6  |
|     |                   | <ul style="list-style-type: none"> <li>– Assignment of rights</li> <li>– Configuration of timeout notice</li> </ul>   |         |
| 5.  | CustomerAdminTool | Miscellaneous   | Page 7  |
|     |                   | <ul style="list-style-type: none"> <li>– Patient login in URL list</li> <li>– Notification of errors in background tasks (c)</li> <li>– More precise labelling of remaining login attempts</li> <li>– Modernised layout</li> </ul>  |         |
| 6.  | FormBuilder       | Simplified data entry   | Page 8  |
|     |                   | <ul style="list-style-type: none"> <li>– Configuration of repetition group tables and subform tables</li> <li>– Configuration of the displayed ordered of repetitions</li> <li>– Configuration of rule violation marks</li> </ul>   |         |
| 7.  | AdminTool         | Simplified participant administration   | Page 10 |
|     |                   | <ul style="list-style-type: none"> <li>– Save option for future centre assignments</li> <li>– Event log for participants and patients</li> <li>– Display login information for participants and patients</li> <li>– Editing of e-mail text for password request (patients)</li> </ul>         |         |
| 8.  | AdminTool         | Simplified resource administration  | Page 12 |
|     |                   | <ul style="list-style-type: none"> <li>– Document upload</li> <li>– Release of multiple resources simultaneously</li> </ul>   |         |
| 9.  | AdminTool         | Assignment of Pat-IDs during patient import   | Page 13 |
| 10. | DataCapture       | Reload in the setup area  | Page 14 |
| 11. | DataCapture       | Simplified data entry   | Page 14 |
|     |                   | <ul style="list-style-type: none"> <li>– Data entry table repetition group</li> <li>– Reversing the order of repetitions (c)</li> <li>– Flagging of rule violations in an item (c)</li> <li>– Linked query / comment symbol</li> </ul>  |         |
| 12. | DataCapture       | Miscellaneous   | Page 16 |
|     |                   | <ul style="list-style-type: none"> <li>– Editing of single visit dates</li> <li>– Deletion of empty, unscheduled visits</li> <li>– HTML tags in (download) document descriptions</li> <li>– Auto-tab configuration for patients</li> </ul>  |         |

- Save confirmation on "My Account" page
- Displayed login information

<b>New Functions</b>
All tools
1. User friendliness

**Automatic password reset for participants (c)**

**sT4.9-2.3, #5791**

In the "Additional features" section of the CustomerAdminTool, it can be configured whether the "Participant password reset" function should also be activated for participants in the customer area of the three tools DataCapture, FormBuilder and ExportSearchTool.

When activated, an additional "Forgotten password" button will appear for participants on the login page. Clicking on this button opens the page for requesting a new password.

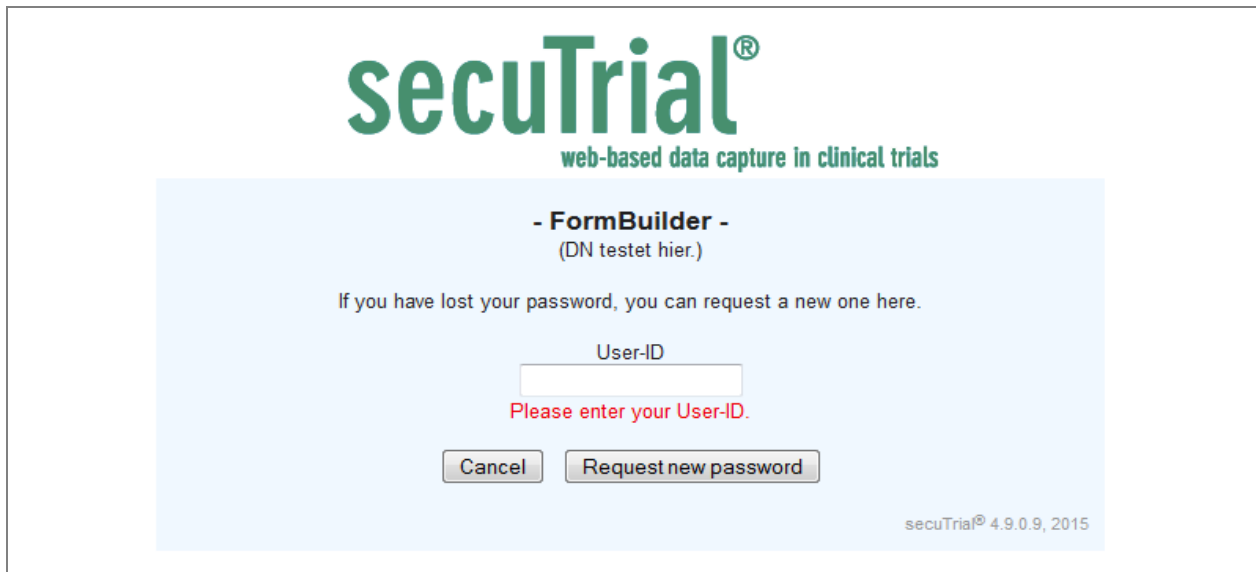


Fig. 1: Page for requesting a new password. If the user ID has already been entered on the login page, this field will be filled accordingly.

If an e-mail address has been saved for the participant, after clicking on the "Request new password" button the participant will receive an e-mail containing a reset URL. Via this URL the participant can create a new password. The URL is valid for 4 hours. In normal situations, passwords will be automatically reset for participants and there is no need to involve an administrator.

If no e-mail address has been registered for the participant, an e-mail will be sent to the e-mail address for the project to which the participant is assigned, either directly or via centres. In the case of multiple projects, all projects will be notified. If no address has been entered for any of the projects or if the participant is not assigned to a project, the e-mail address registered for the customer will be used. If no address can be determined, no e-mail will be sent.

After clicking on the request password button, the participant will be informed of the respectively performed action. The e-mail will be sent in the language used by the participant if a language has been configured. Otherwise the language displayed on the request password page will be used. The subject and content cannot be configured.

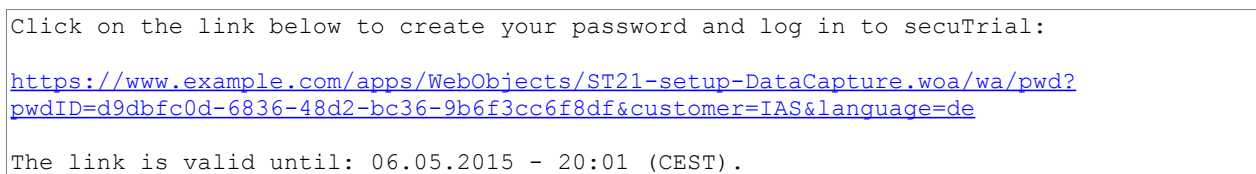


Fig. 2: Example of an e-mail sent to a participant with a link for creating a password.

After creating a password, on the next page a link will be displayed to the login page of the tool from which the request was made.

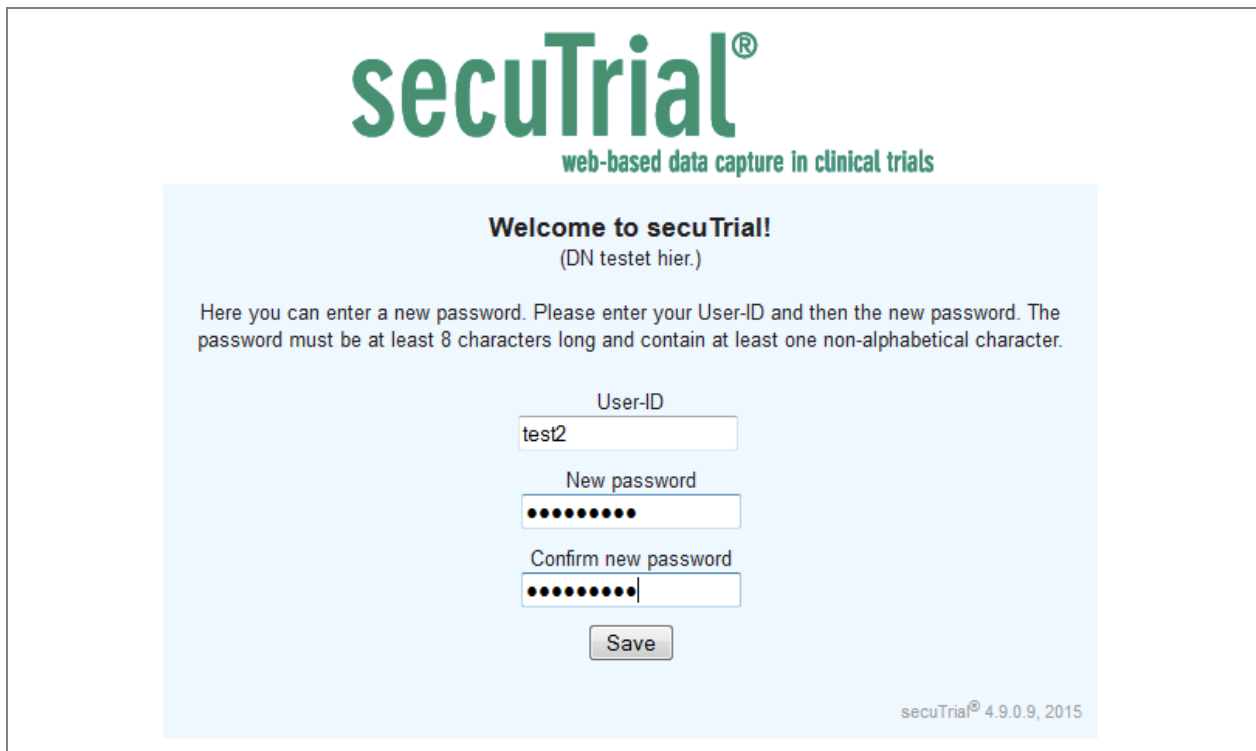


Fig. 3: Page for creating a new password (accessed via the e-mailed link).

### Remaining session time displayed on the page

#7692, #7162

In addition to being shown in the browser title, the time remaining until the current session expires will also be displayed in red on the page in the status bar or menu bar. In DataCapture the remaining time will be shown on the top right of the screen above the menu options (see Fig. 20). In the other tools the remaining time is displayed towards the middle of the screen, next to the name of the currently logged in user (see Fig. 4).

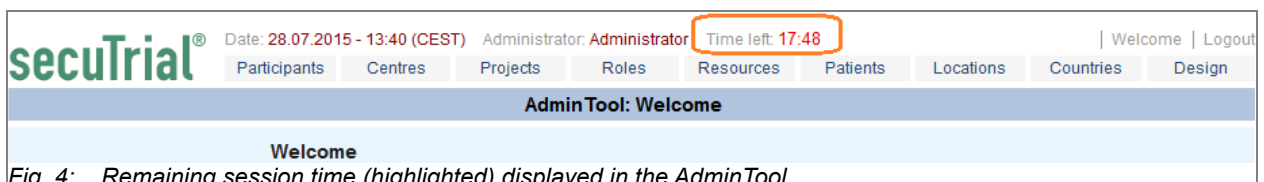


Fig. 4: Remaining session time (highlighted) displayed in the AdminTool.

### Error pages

sT4.9-5, #5198, #4049

The appearance and phrasing of the general error page have been optimised. The technical details of the error (StackTrace) are now only displayed after clicking on the "Show details" link or if the error page is printed out from the browser.

In addition, it is now possible to write an error report in a free text field. If an e-mail address for "error.admin" has been entered in the configuration file of the tool, the error report can be sent from the server to this e-mail address. If an e-mail address has not been entered, the report page and technical details can be printed and passed on via a different method.

secuTrial® Date: 12.10.2015 - 12:00 (CEST) Participant: Dipl. Biol. Susanne Schneider | Print | Back

**ERROR!**

**DataCapture <dev. version>**  
Customer: interActive Systems (IAS)

An unexpected error has occurred, that should not have happened!  
You could help us resolving this issue if you describe us the circumstances leading to this error.  
You can use the function "Send error report" on this page.

Please give a description of the error occurrence:

Send error report Back

[Hide details](#)

The error is described as below:

```
[12.10.2015 12:00:51] - de.secutrial.dc.pages.EntranceWelcomeFrame - - - [<de.secutrial.dc.pages.EntranceWelcomeFrame name: de.secutrial.dc.pages.EntranceWelcomeFrame
subcomponents: {0 = <de.secutrial.dc.components.MenuPageWrapper name: de.secutrial.dc.components.MenuPageWrapper subcomponents: {0.29.EntranceMenuFrame =
<de.secutrial.dc.components.EntranceMenuFrame name: de.secutrial.dc.components.EntranceMenuFrame subcomponents: {0.29.EntranceMenuFrame.2.11.7.1.13 =
<de.secutrial.dc.components.StatusDisplayComponent name: de.secutrial.dc.components.StatusDisplayComponent subcomponents: null >; } >; 0.21.EntranceMenuFrame =
<de.secutrial.dc.components.EntranceMenuFrame name: de.secutrial.dc.components.EntranceMenuFrame subcomponents: {0.21.EntranceMenuFrame.2.11.7.1.13 =
<de.secutrial.dc.components.StatusDisplayComponent name: de.secutrial.dc.components.StatusDisplayComponent subcomponents: null >; } >; } >; 0.27.3 =
<de.secutrial.dc.components.ProjektDocumentsComponent name: de.secutrial.dc.components.ProjektDocumentsComponent subcomponents: null >; } > valueForKey(): lookup of
unknown key: 'sx'. The WOComponent de.secutrial.dc.pages.EntranceWelcomeFrame does not have an instance variable of the name sx or _sx, nor a method of the name sx,
_sx, getSx, or _getSx
```

Fig. 5: Example of an error page with the option to write an error report and display details (StackTrace).

The same error page will also be displayed if an attempt is made to call up a non-existing DirectAction (unknown URL in the application) without a valid login. In this case the option to write an error report will not appear.

### Auto-tab option and calendar in all date fields

**sT4.9-1.1, #4554, #6009**

The configuration for the Auto-Tab option has now been taken into account for all date field entries outside of an eCRF. The configuration is tested in the order:

- Participant / patient setting
- Project design
- Customer design

The participant or patient setting can also be set so that the configuration will be used in the design. If a project design already exists and if a project is currently selected, this design will be used.

A helpful calendar can now be called up for all date fields by clicking on the small icon next to the entry fields. For date and time fields within an eCRF, the icon is only displayed if a date (and not only a time) can actually be entered.

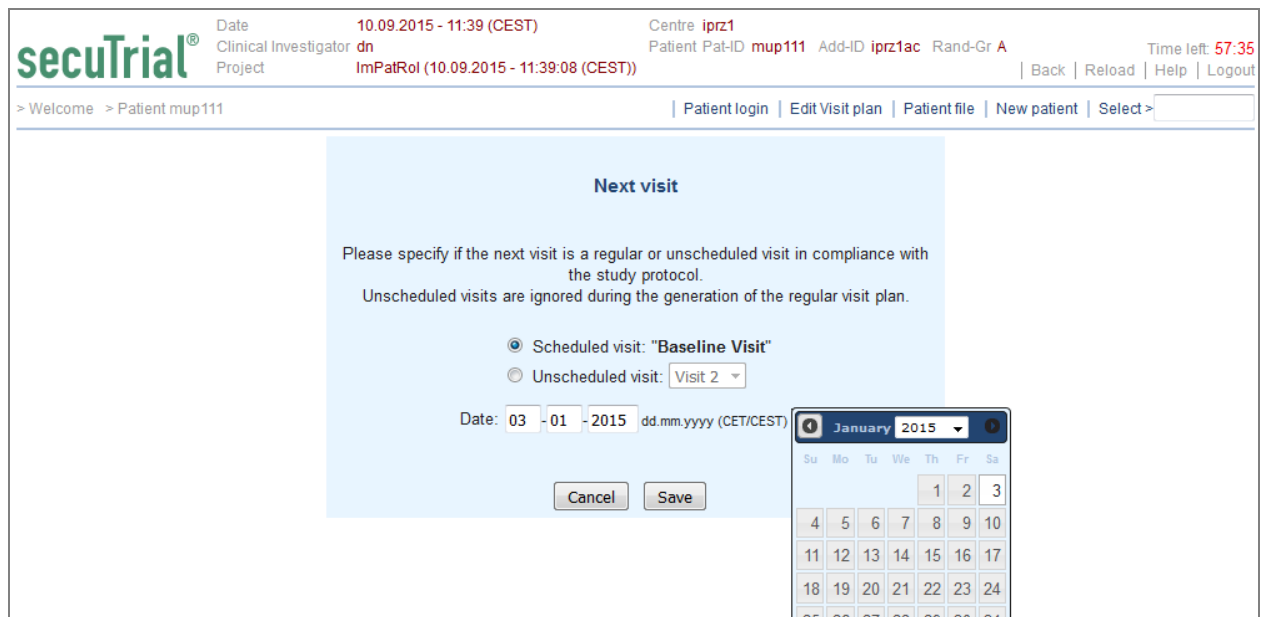


Fig. 6: Calendar for creating a new visit.

### Multiple attempts at sending an e-mail

#7494

In secuTrial® e-mails can be triggered by various events. The sending of e-mails always takes place via a separate e-mail server which is specified in the secuTrial® configuration files.

If an e-mail fails to be sent in secuTrial®, for example because the e-mail server is not available, the attempt to send the e-mail will be repeated up to two times. The attempts will take place at intervals of 3 and 5 minutes.

These multiple attempts will only be performed if secuTrial® has previously registered a problem with sending e-mails. For example, this would be the case if the e-mail server had crashed or the necessary Internet connection to these servers was not available. Invalid e-mail addresses which are first noticed by the receiving e-mail server cannot be dealt with in this way.

CustomerAdminTool
2. Update history and configuration display <span style="float: right;">sT4.9-6, #4733, #7012</span>

In the CustomerAdminTool there is now a new menu option "Info". Clicking on this displays the update history of secuTrial® and all of the currently active configurations of the tool. As updates have been logged in the database since secuTrial® version 2.3, in older installations this new overview also displays the history retroactively to this point.

The displayed configuration details correspond with the information that used to be accessible via the URL attachment "[Tool].woa/wa/status". The configuration information is divided into four sections:

- 1) Java information
  - Start parameter WOMonitor
  - Java VM
  - Available memory
- 2) Configuration file
  - Entries from secuSuite.cfg
  - Entries from CustomerAdminTool.cfg
- 3) Environment variables
  - All Java system properties
  - All WO system properties
  - All secuTrial® properties set by start parameters
- 4) Database

- Oracle version
- Internet connection configuration
- Number of customers, schemas and projects
- Current data models

The screenshot shows the 'Info' page in the secuTrial application. At the top, it displays the date '10.09.2015 - 11:55 (CEST)', user 'admin', and time left '17:59'. There are navigation links for 'Customers', 'Administrators', 'Schemas', 'Background', 'History', 'Documentation', and 'Info'. The main content is divided into two sections:

Update history	Application version number	Application installation date	Database version number
	4.9.0.12	03.09.2015 - 16:31 (CEST)	7
	4.9.0.11	08.08.2015 - 17:44 (CEST)	7
	4.9.0.10	30.07.2015 - 14:12 (CEST)	7
	4.9.0.9	28.05.2015 - 15:37 (CEST)	7
	4.9.0.8	13.05.2015 - 00:56 (CEST)	7
	4.9.0.7	23.04.2015 - 16:56 (CEST)	7
	4.9.0.6	15.04.2015 - 15:54 (CEST)	7
	4.9.0.5	25.03.2015 - 22:27 (CET)	7

Below the table is a section titled 'Configuration STS04-setup-CustomerAdminTool' with the following details:

- Application Name: STS04-setup-CustomerAdminTool
- Application Version: 4.9.0.12
- Application BuildTag: srt\_4\_9\_0\_12
- Application Build Number: \${env.BUILD\_NUMBER}
- Application Host: srv02.asps.interactive-systems.de
- Application Port: 3010
- Application Number: -1
- Application Path: /opt/Apple/Local/Library/WebObjects/Applications/STS04/CustomerAdminTool.woa
- Application Startup Time: Thu Sep 10 02:00:06 GMT+00:00 2015

Fig. 7: New information page showing performed installation updates and all CustomerAdminTool configuration options (excerpt).

Note: The information displayed here is only valid for this CustomerAdminTool. Other tools may be configured differently; for all productive tools the entries from the "productive.secuSuite.cfg" file in particular apply. If applicable, the active options can be displayed via the status URL (see above) of the respective tool (always log in with the CustomerAdminTool user ID and password).

3. Configuration of automatic password reset for participants sT4.9-2.3, #5791

The newly introduced function for the automatic sending of passwords for participants (see section Automatic password reset for participants (c) sT4.9-2.3, #5791 above) can be activated separately for each customer area. For this purpose, a new configuration option has been introduced in the section "Additional features" on the customer editing page.

For existing or newly created customers this function is initially deactivated.

The screenshot shows the 'Additional features' section of the customer editing page. It contains several checkboxes with question marks:

- Patient file ?
- Hide ?
- My Account ?
- Pseudonym Display ?
- Participant password reset

The 'Participant password reset' option is highlighted with a red circle.

Fig. 8: New configuration option (highlighted) in the customer's additional features section.

4. Activity log sT4.9-2.2

**Assignment of rights**

**#7832**

To view the event log, an additional right must be assigned to administrators for participants and patients separately. This right can only be assigned if the general participant administration right has been assigned, otherwise the corresponding check boxes will not be visible (if the general participant adminis-

tration right is deselected, the right to assign randomization numbers to centres will now also be removed and will no longer be visible.)

Fig. 9: Assignment of rights on the editing page for administrators.

Without the assigned right, the button for viewing the event logs of participants and patients will not be displayed. However, the logs will always be recorded regardless of the assigned rights.

The assigned rights are listed with abbreviations on the administrator overview page. In the database all rights are summarised in a column (bit mask) as follows:

- 1 Participant administration
- 2 Random number assignment per centre
- 4 Random administration
- 8 Event log participants
- 16 Event log patients

### Configuration of the timeout notice

#7834

It is possible to configure that a short notice should be displayed for the first login following the expiry of a session without logging out. This can be done for each customer in DataCapture and in the FormBuilder and ExportSearchTool (see Displayed login information sT4.9-2.2, #5675, #7763, #3800).

Fig. 10: New configuration option (highlighted) for displaying a timeout notice in DataCapture, FormBuilder and ExportSearchTool.

## 5. Miscellaneous

### Patient login in URL list

#4205

The URL for the patient self-documentation login page has been added to the list in the "Show URLs" popup window. The appended words "participants" and "patients" indicate the different uses of the two URLs.

### Notification of errors in background tasks (c)

#4545

An e-mail address for error notifications (see "Error pages sT4.9-5, #5198, #4049") can be entered in the configuration files. When an address has been entered, an e-mail containing technical details (Stack-Trace) will also be sent to this address in the event of errors (exceptions) in CustomerAdminTool background tasks. This applies for the following actions:

- Bundled message dispatches (queries, visits)
- Automatic report exports
- Automatic imports
- Generation of statistics

### More precise labelling of remaining login attempts

#7651

The number of remaining attempts for entering the correct password to login and for the e-signature (see also: Event log for participants and patients sT4.9-2.2, #5675, #7763, #3800 and Displayed login information sT4.9-2.2, #5675, #7763, #3800) has been more precisely labelled. An online help text explains this configuration option.

### Modernised layout

#7653

The menu layout of the CustomerAdminTool has been adjusted to the layout of DataCapture (see Fig. 7).

FormBuilder
6. Simplified data entry

### Configuration of repetition group tables and subform tables

sT4.9-1.3

#6266

For the tabular display of a subform (see Fig. 21) a new question component type has been introduced, the IAS table repetition group. In this repetition group only a newly introduced subform type with "Table layout" (see Fig. 13) can be used.

In this question component, the question and item labels of the subform are displayed only once directly in the outer table repetition group as table column headings. In the repetition rows, only the entry elements and the units/labels will then be displayed. If no title is entered for display in the form, the subheading in the table repetition group will be omitted (see Fig. 21 bottom example).

Fig. 11: Configuration of an IAS table repetition group (new configuration option for the order of repetitions highlighted, see below: Configuration of the displayed order of repetitions sT4.9-1.2, #6143).

To provide a more compact view, instead of a "Delete" button a trash can icon will be used for this repetition group. In the online help next to the entry field for the "More" button icon, a preview is available of the alternatively available secuTrial® icons for both buttons.

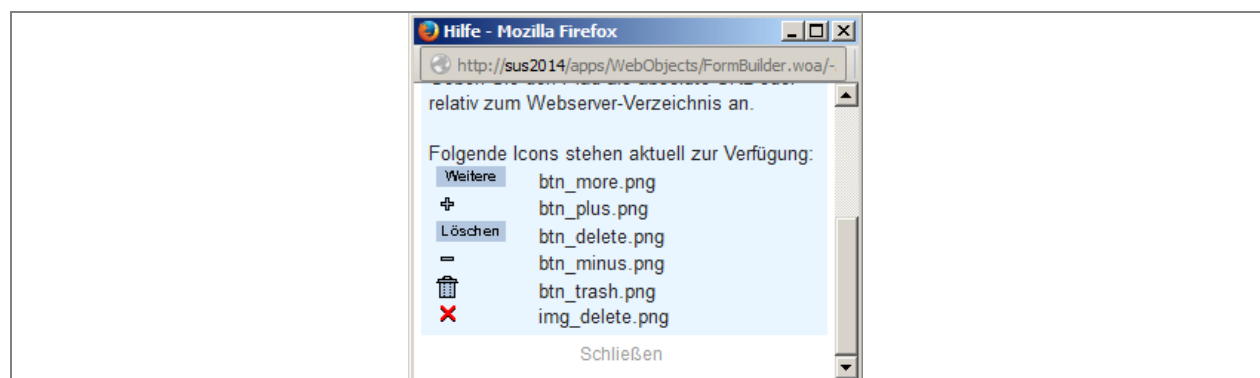


Fig. 12: Online help function for the button icons of repetition groups.



To use these existing images simply enter the file name. These icons will also be adjusted for display in different languages (for buttons with text) or designs (different colour) according to the current settings.

It also possible to reference any files you wish from the local web server. To do this, the relative path is to be entered from the web server directory of the application (the document root directory of the web server is accessed via "../.." at the beginning). In this case the same buttons will be used for all languages and design settings.

Note: It is possible to modify the button icons for both repetition group component types.

As only a complete row with items can be displayed in a table repetition group and the layout settings of the subform question defined in the subform are ignored, the new subform processing option "Table layout" has been introduced for use in the new question components. The table subform can also be used in a normal repetition group.

This subform type must only contain a single question of the type IAS horizontal group. As long as this subform is used in a table repetition group, this subform configuration cannot be modified, the question type cannot be changed and no other questions can be created within this form.

The screenshot shows a configuration form for a subform. The 'Form name (overview):' field contains 'Medical History'. Under 'Processing:', the 'Table layout' checkbox is checked and highlighted with an orange box. The 'Database table:' field contains 'emnpt4mh'. The 'Displayed order:' field contains '20'. The 'Form name (title):' field also contains 'Medical History'. Below these fields, it says 'Form used in: (1) Medical History <mnpt4mh>'. At the bottom, there is a table titled 'Included questions (1)'. The table has columns for 'Displayed order', 'Shown no.', '+ / - Question', 'Type', and 'Delete from database'. One row is visible with '10' in the first column, an empty box in the second, a '+' sign and 'Medical History' in the third, 'IASHorizontalGroup' in the fourth, and a 'Delete' button in the fifth. Below the table are 'Overview Items' and 'Organize questions' buttons.

Fig. 13: Configuration of a table subform (highlighted).

### Configuration of the displayed order of repetitions

**sT4.9-1.2, #6143**

For the two repetition group question components, it can now be configured whether the repetitions should be displayed in the normal order as has been the case so far (most recent repetition at the bottom) or vice-versa (most recent repetition at the top, see Fig. 11).

If the order is reversed, the "More" button will be displayed above the repetitions. New repetitions will then be added at the top. The order numbering remains as before; the repetitions will be consecutively numbered in their order of creation (see Fig. 21).

The repetition group display view can also be subsequently changed. The order of the displayed data will be accordingly reversed, the position numbers will remain the same.

### Configuration of rule violation marks

**sT4.9-1.4, #6282**

On the form editing page you can configure how the rule and validation check should be performed for all saved main forms. In addition to the already existing option "immediate validation (error message)" with the full error message displayed, the new option "immediate validation (mark)" has been introduced. Both options can be selected together, even if this is perhaps not especially useful in terms of content.

For a description of the behaviour when this option is selected, please read the section on DataCapture: Flaggering of rule violations in an item (c) sT4.9-1.4, #6282.

**Validation and rules:**

Markup (rule based) mandatory fields
  check of completion ?
 immediate validation (error message)
  immediate validation (mark) ?

Please correct the marked invalid data. Form error message (Default)

Please check marked entries before saving. Form confirmation message (Default)

Fig. 14: Configuration of the rules and validation check in the form (highlighted: new option).

**AdminTool**

**7. Simplified participant administration**

**Save option for future centre assignments**

**sT4.9-2.4, #6306**

If a participant is to be assigned to all centres in a project, after selecting "all centres of project", an additional list will offer the options

- only for current centres
- also for future centres

All projects with "future" will be displayed above the list with the selected role and this selection can also be deleted here. The actual roles in the individual centres can be selected independent from this future assignment.

If a new centre is created for this project, all participants for which this future assignment has been saved will now be automatically added with the role entered there for the centre. The participant can also be subsequently removed from centres of this project. The "future" assignment is only evaluated directly when creating a new centre.

▶ Location:  
 ▶ Bank info:  
 ▶ Preferred language:

Centres: (6)

Project	Centre	Role	Status
ImPatRol (IPR)	iprz1	Clinical Investigator	<input type="radio"/> active <input type="radio"/> inactive <span>Remove</span>
	IPRZ1	Clinical Investigator	<input checked="" type="radio"/> active <input type="radio"/> inactive <span>Remove</span>

Add project or centre: AA (T8) all centres of project

only for current centers  
 only for current centers  
 for future centers

Fig. 15: Selection (below) and display (above) of the future centre assignments for participants.

**Event log for participants and patients**

**sT4.9-2.2, #5675, #7763, #3800**

All participant or patient events that involve entering a password or are related to the activity status of a participant or patient are saved as events in a new table in the database. A number of activities are only performed by the participants or patients themselves, others can also be performed by the administrator in the AdminTool. The triggering user is therefore listed separately in the log.

The following events are currently logged:

<i>Event</i>	<i>Description</i>	<i>Type</i>
Created	The participant or patient was newly created.	Status
Deactivation	The participant has been completely deactivated or only inactivated in a centre (manually in the AdminTool or by entering an incorrect password multiple times). The patient login status of the patient was set to "Password frozen" (incorrect password multiple times).	Status
Activation	The participant was activated globally or in a centre. In the case of an event change in the centre, all centres are listed as an object. Patient has created a password and can login.	Status
Candidate	The participant was assigned to a project with a qualification test directly or indirectly via centres or the status was directly set to "Candidate" (only for participants).	Status
Deletion	The participant or patient was set to the status "to be deleted". <b>Note:</b> If the deletion is actually carried out, the related event log will also be deleted!	Status
Login	The participant or patient successfully logged in to Data-Capture (patient, participant), the FormBuilder (participant) or the ExportSearchTool (participant).	Login
Logout	The participant or patient logged out (via the menu button).	Login
Login rejected	Despite entering the correct password, the login was rejected either because insufficient role rights or the wrong login status.	Login
Login incorrect password	The participant or patient entered an incorrect password when logging in. After multiple (number configurable) incorrect password entries the participant or patient was inactivated.	Login
Session expired	The session ended because the time had expired without the participant or patient logging out.	Login
Session ended due to double login	If a participant or patient logs in to the same tool again in the same browser during an ongoing session, the old session will be automatically ended.	Login
Password reset	The participant or patient has reset his or her password via a password URL (old password unknown).	Password
New password requested	The participant or patient requested a new password.	Password
Password reset activated	Only for patients: the patient login status was set to "New password can be entered". This is done either through activation when setting up a new login or by clicking on the "create password" button after a new password has been requested by the patient.	Password
Password changed	The participant or patient has reset his or her password (old password unknown).	Password
E-signature	The e-signature was implemented through entry of the correct password.	E-signature
E-signature incorrect password	An incorrect password was entered for the e-signature (save not possible). After multiple (number configurable) incorrect password entries, the participant or patient was inactivated.	E-signature

The log can be viewed from the editing pages of the participant or patient via the menu bar at the bottom. In the log it is possible to change the displayed participant or patient or to display all participants or

patients. The log is displayed page by page, the number of entries per page can be configured via the page number display for each session. The display can also be filtered by event and/or type. The log also can be downloaded as an Excel file.

The screenshot shows the 'Eventlog' section of the secuTrial application. At the top, there are navigation tabs: Participants, Centres, Projects, Roles, Resources, Patients, Locations, Countries, Design, and Randomization. The 'Eventlog' title is centered. Below it, there are filters for Participant (dn <dn>), Type (< Please choose >), and Event (< Please choose >). The main area is a table with columns: Date, Type, Event, Object, Tool, User, and Host. The table contains 18 rows of event data. At the bottom, there are 'Back' and 'Excel' buttons, and a 'Page 1 of 45' indicator.

Date	Type	Event	Object	Tool	User	Host
10.09.2015 - 15:04:41 (CEST)	Login/-out	Session timeout	-	FormBuilder	dn <dn>	217.9.63.114
10.09.2015 - 14:16:20 (CEST)	Login/-out	Login	-	FormBuilder	dn <dn>	217.9.63.114
10.09.2015 - 14:16:19 (CEST)	Password	Password Change	-	FormBuilder	dn <dn>	217.9.63.114
10.09.2015 - 14:16:02 (CEST)	Login/-out	Login rejected	-	FormBuilder	dn <dn>	217.9.63.114
10.09.2015 - 14:15:50 (CEST)	Login/-out	Login rejected	-	FormBuilder	dn <dn>	217.9.63.114
10.09.2015 - 12:40:18 (CEST)	Login/-out	Session timeout	-	DataCapture	dn <dn>	217.9.63.114
10.09.2015 - 11:59:41 (CEST)	Login/-out	Session timeout	-	FormBuilder	dn <dn>	217.9.63.114
10.09.2015 - 11:38:01 (CEST)	Login/-out	Login	-	FormBuilder	dn <dn>	217.9.63.114
10.09.2015 - 11:19:41 (CEST)	Login/-out	Session timeout	-	FormBuilder	dn <dn>	217.9.63.114
10.09.2015 - 10:59:26 (CEST)	Login/-out	Login	-	FormBuilder	dn <dn>	217.9.63.114
10.09.2015 - 10:58:52 (CEST)	Login/-out	Login	-	DataCapture	dn <dn>	217.9.63.114
09.09.2015 - 10:45:19 (CEST)	Login/-out	Session timeout	-	DataCapture	dn <dn>	217.9.63.114
09.09.2015 - 09:44:33 (CEST)	Login/-out	Login	-	DataCapture	dn <dn>	217.9.63.114
02.09.2015 - 11:04:39 (CEST)	Login/-out	Session timeout	-	FormBuilder	dn <dn>	217.9.63.114
02.09.2015 - 10:35:56 (CEST)	Login/-out	Login	-	FormBuilder	dn <dn>	217.9.63.114

Fig. 16: Event log of a participant.

### Display login information for participants and patients

#7641

As all login attempts are now logged in the database (see: Event log for participants and patients sT4.9-2.2, #5675, #7763, #3800), it is also possible to display the time of the participant's/patient's last login and the number of failed login attempts since the last successful login.

The screenshot shows a table of patient login information. The fields are: Pat-ID: mip124, Add-ID: iprz1aa, Status: active (with an 'Edit status' button), Login: New Password can be entered (with an 'Edit login' button), and Last Login: 04.08.2015 - 14:28:36 (CEST) There where 4 failed login tries since the last login.

Pat-ID:	mip124	
Add-ID:	iprz1aa	
Status:	active	<input type="button" value="Edit status"/>
Login:	New Password can be entered	<input type="button" value="Edit login"/>
Last Login:	04.08.2015 - 14:28:36 (CEST) There where 4 failed login tries since the last login.	

Fig. 17: Displayed login information on the patient editing page.

### Editing of e-mail text for password request (patients)

#7505

When a new patient password is requested in the patient self-documentation, an e-mail is sent to the e-mail address that has been entered for the centre. The title (=subject) and content of this e-mail can now be edited in the AdminTool under the menu item Design in the section "E-mails for patient login".

The placeholder "<USER-ID>" can be used in the texts. This will be replaced with the patient pseudonym when the e-mail is sent. The pseudonym will be used in the order Pat-ID, Add-ID or Lab-ID which is displayable according to the customer, project and role configuration of the patient.

The language of patient will be used in the e-mail if a separate language has been configured for the patient. Otherwise the currently used language of the page will be used (usually the language of the customer area).

## 8. Simplified resource administration

### Document upload

sT4.9-3.1, #5640

On the overview page for resource rights there is now a button for adding files below the listed project documents.

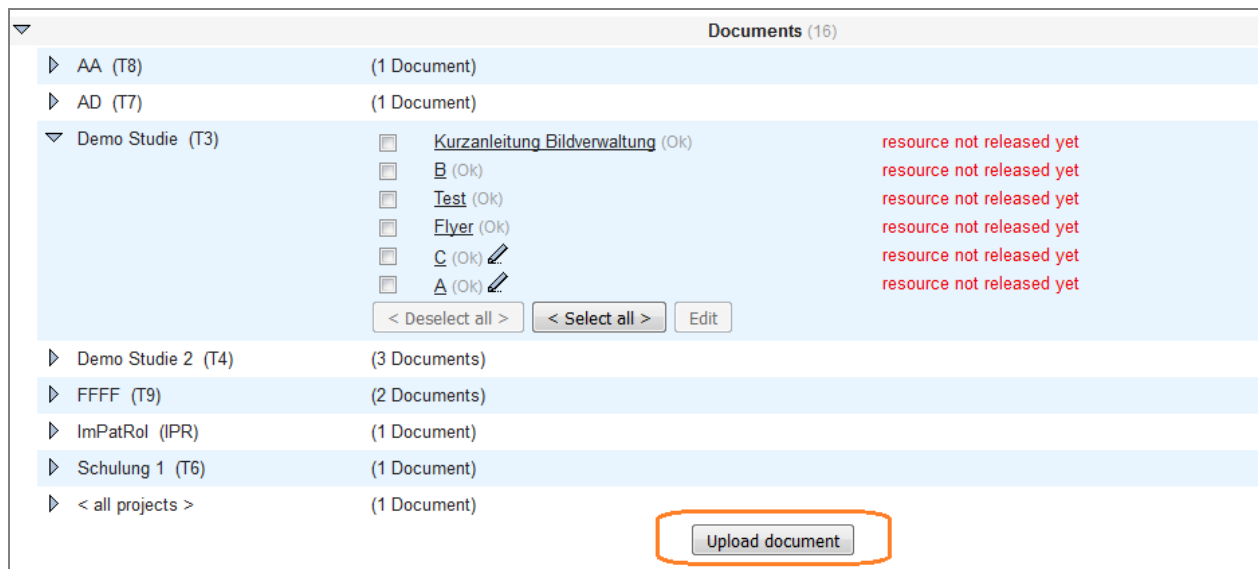


Fig. 18: All documents in the resource overview. Documents that have been uploaded and can be edited in the AdminTool are indicated with a pencil symbol. Clicking on this button (highlighted) opens the editing page for a new document.

On the document editing page you can then select whether the uploaded file should be available only for one project or for all projects. The displayed name and additional description can likewise be entered here (both entries can be formatted with HTML).

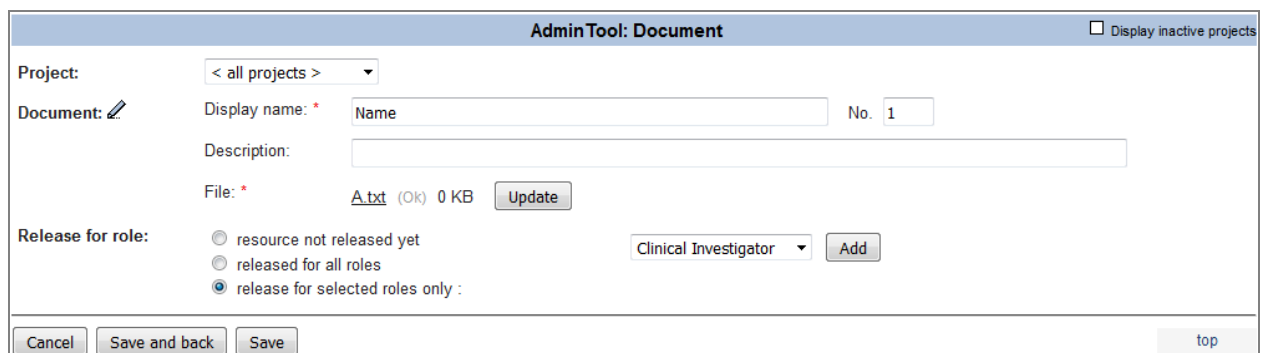


Fig. 19: Editing page for a document uploaded in the AdminTool.

Documents assigned to inactive projects can no longer be edited and no new documents can be directly assigned to these projects. When a project is archived, all documents uploaded in the AdminTool that are directly assigned to the project or to all projects will also be archived.

The assignment of rights to these documents is performed in exactly the same way as for the documents linked to the project version in the FormBuilder.

Note: Documents uploaded in the AdminTool are independent from the version management of the projects; they will not be transferred from the setup to the productive area even if the project is released and set to productive mode!

### Release of multiple resources simultaneously

**sT4.9-3.2, #6288**

In the resource overview multiple resources of the same type can now be selected simultaneously for editing via the checkboxes. It is also possible to select or deselect all of them via two buttons below the list (see Fig. 18).

All selected resources will then be listed at the top of the editing page. The performed change in rights will be conducted for all of these resources.

### 9. Assignment of Pat-IDs during patient import

**sT4.9-4, #6281**

When importing patient lists and creating new patients, the Pat-IDs will now be automatically assigned if only the Add-IDs are entered in the import (empty Pat-ID column).

If no Pat-ID has been entered but a patient already exists with the entered Add-ID, the patient will be rejected in the analysis as already created.

DataCapture	
10. Reload in the setup area	sT4.9-7, #6031

In the DataCapture setup area, a "Reload" button has now been added to the general menu at the top right of the screen (see Fig. 20).

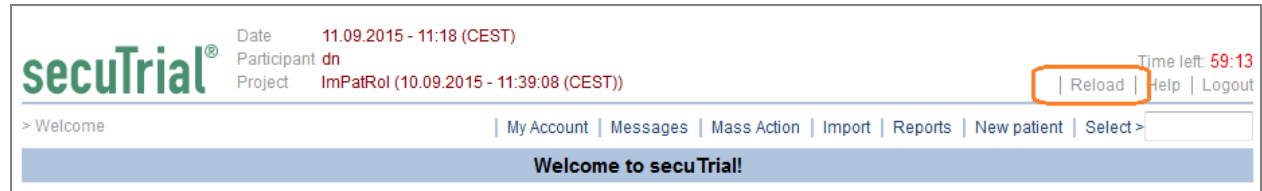


Fig. 20: Menu bar in the DataCapture setup with new "Reload" button (highlighted) and the remaining session time displayed in red (top right).

When this button is clicked, all data from the database is re-read and any changes made in the FormBuilder, AdminTool or participant administration (role rights) will be reloaded.

Any open windows, e.g. for reports or query processing will be closed. If the displayed page is no longer valid after the reload, e.g. because the opened form was deleted, the next highest displayable level will be shown. If the displayed form is deleted, the form overview of the patient will be displayed. If the patient has also been deleted or if only the display rights for the patient have been deleted (e.g. due to a centre change), the DataCapture welcome will be displayed again.

In the case of simple additions, e.g. an additional form component, the displayed form will be retained. However, all entered but not yet saved data will be deleted.

11. Simplified data entry

**Data entry table repetition group sT4.9-1.3, #6266**

In a table repetition group all item texts are listed just once above the data entry rows. The texts (label and description texts) of the horizontal group of the table sub form are likewise displayed just once above the data entry table.

Each repetition is displayed in a row of the table. The delete button is displayed as a trash can icon in front of each row (the icon can also be changed per repetition group, see FormBuilder: Configuration of repetition group tables and subform tables sT4.9-1.3 #6266). Next to it is the number of the order, followed by the data entry elements and lastly the menus for queries and comments.

Data entry is otherwise carried the same way as in the previous repetition group: via the button "More" new repetitions can be created. If the "Delete" button has been configured, the respective row can be completely deleted using the trash can icon (providing no query / comment exists and more than the minimum number of repetitions has been created).

The screenshot shows a form titled 'Medical History' with document number '745 - 1'. It features two repetition groups. The first group, 'Medical History', has three rows, each with a trash icon, a minus sign, a date field (dd.mm.yyyy), and a calendar icon. The second group, 'Concomitant Medication', is titled 'Repetitions (reverse order)' and has three rows. Each row includes a trash icon, a minus sign, a text field for 'Trade Name', a minus sign, a text field for 'Indication', a minus sign, a date field for 'Date of Start', a radio button for 'Ongoing' (yes/no), a minus sign, and a date field for 'Date of End'. A 'More' button is located above the 'Concomitant Medication' group.

Fig. 21: Form excerpt with two table repetition groups. In the bottom question the repetitions are configured in reverse order and the subform has no specified form title.

**Reversed order of repetitions (c)**

**sT4.9-1.2, #6143**

When the order is reversed (see Fig. 21, bottom repetition group) the "More" button is shown above the repetitions and the repetitions are displayed in descending order of creation (most recently created repetition at the top).

The reversed repetition can be configured both for the old repetition group and for the newly introduced table repetition group.

**Flagging of rule violations in an item (c)**

**sT4.9-1.4, #6282**

During validation, if the option "immediate validation (mark)" has been configured for a form, when the form is displayed after executing the rule check, instead of error and warning messages only a red (error) or grey (warning) exclamation mark will be shown next to the respective item.

The screenshot shows a form with several fields. 'Date of birth' has a grey exclamation mark and a date field (tt.mm.jjjj). 'Gender' has a grey exclamation mark and radio buttons for 'male' and 'female'. 'Ethnicity' has a grey exclamation mark and a dropdown menu with '< Bitte auswählen >'. 'Body weight' has a grey exclamation mark and a text field followed by 'kg'. 'Body height' has a grey exclamation mark and a text field followed by 'cm'. 'Body Mass Index' has a grey exclamation mark and a 'Score' button. Below these is a 'Short text field' with a grey exclamation mark and a text input area.

Fig. 22: Excerpt of a form with different items and marked rule violations. For the item "Short text field" only a confirmation rule was violated, therefore a grey exclamation mark for warnings is shown.

When the "Save" button is clicked, the normal validation is performed and the error and warning messages for the rule violations will be additionally displayed in words.

**Linked query / comment symbol**

**sT4.9-1.5, #6327**

In the form, a question in which a query or comment has been created in relation to an item is indicated with a small symbol on the left edge of the form.

Via this symbol the editing window for queries or comments can be opened, just like via the menu on the right-hand edge of the form.

12. Miscellaneous

**Date changes of individual visits**

**sT4.9-8, #6285**

When editing the visit plan of individual patients, it is now possible to select whether a visit date change should shift all subsequent visits or whether the date change should only be applied to the changed visit (upper area highlighted in Fig. 23).

After clicking on the "Preview" button, the new visit plan will be changed accordingly and checked according to the specifications in the project visit plan template. It may not be possible to save the modified visit plan if changing just one visit date means that the chronological order of the visits no longer corresponds with their order of creation and if this is not permitted by the project configuration.

**Deletion of empty, unscheduled visits**

**#6328**

Unscheduled visits for which no data has been collected can now be deleted in any order (see Fig. 23). Unscheduled visits are consecutively numbered per type in the order of creation. If visits in the middle are deleted, gaps will therefore appear in the order. If you do not want this to happen, during the deletion process you can select whether the numbering of these unscheduled visits should be adjusted to the order after deletion (see lower highlighted area in Fig. 23).

Both the deletion and the order adjustment will be recorded in the visit plan history. The history has also been slightly optimised.

Fig. 23: Extended editing options for the visit plan (highlighted).

**HTML tags in (download) document descriptions**

**#7312**

For the displayed name and description texts of documents uploaded in the FormBuilder or AdminTool for a specific project or for all projects, it is now possible to enter HTML formatting. This HTML formatting is interpreted in DataCapture and the displayed text will be formatted accordingly (see also Fig. 18 and Fig. 19).





Fig. 24: Download area in DataCapture (example). Documents valid for all projects are shown first, followed by the project documents.

**Auto-tab configuration for patients**

**#5959, #7723**

Patients can now configure the auto-tab behaviour for multiple entry fields (numbers with decimal points and date/time fields) on their "My Account" page.

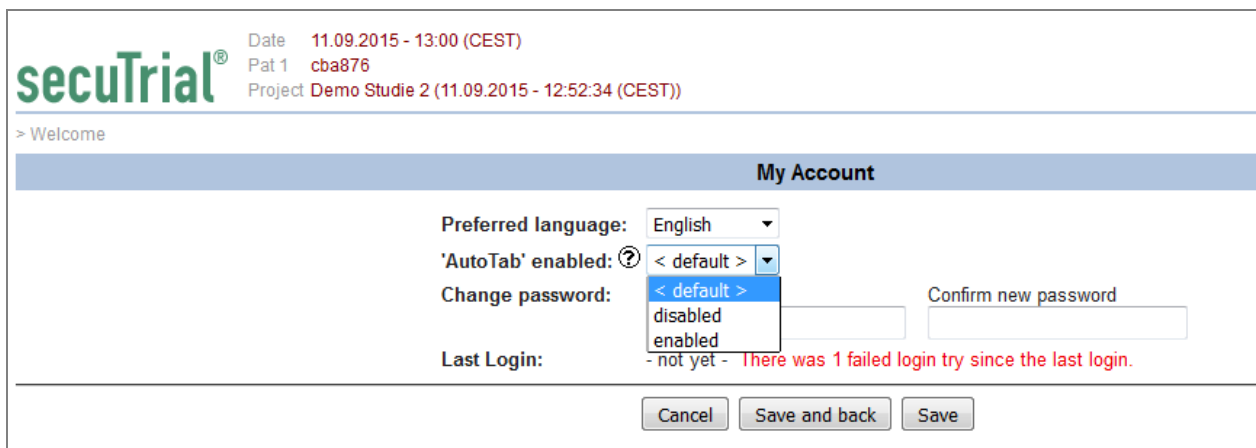


Fig. 25: "My Account" page for patients with auto-tab configuration option and login information.

**Save confirmation on "My Account" page**

**#7659**

When save is clicked on the "My Account" page, the blue message "The data has been saved." is now displayed as in all other tools if the saving process was successfully carried out (see Fig. 25).

**Displayed login information**

**sT4.9-2.2, #5675, #7763, #3800**

When logging in to DataCapture, FormBuilder and ExportSearchTool it is checked whether the last session was properly ended by logging out or whether it was ended due to a timeout and a timeout message has been configured for the customer. In the latter case, the user will be informed of this with a Javascript pop-up window and asked to logout properly. After confirming the Javascript message, the normal welcome page of the tool will be displayed.

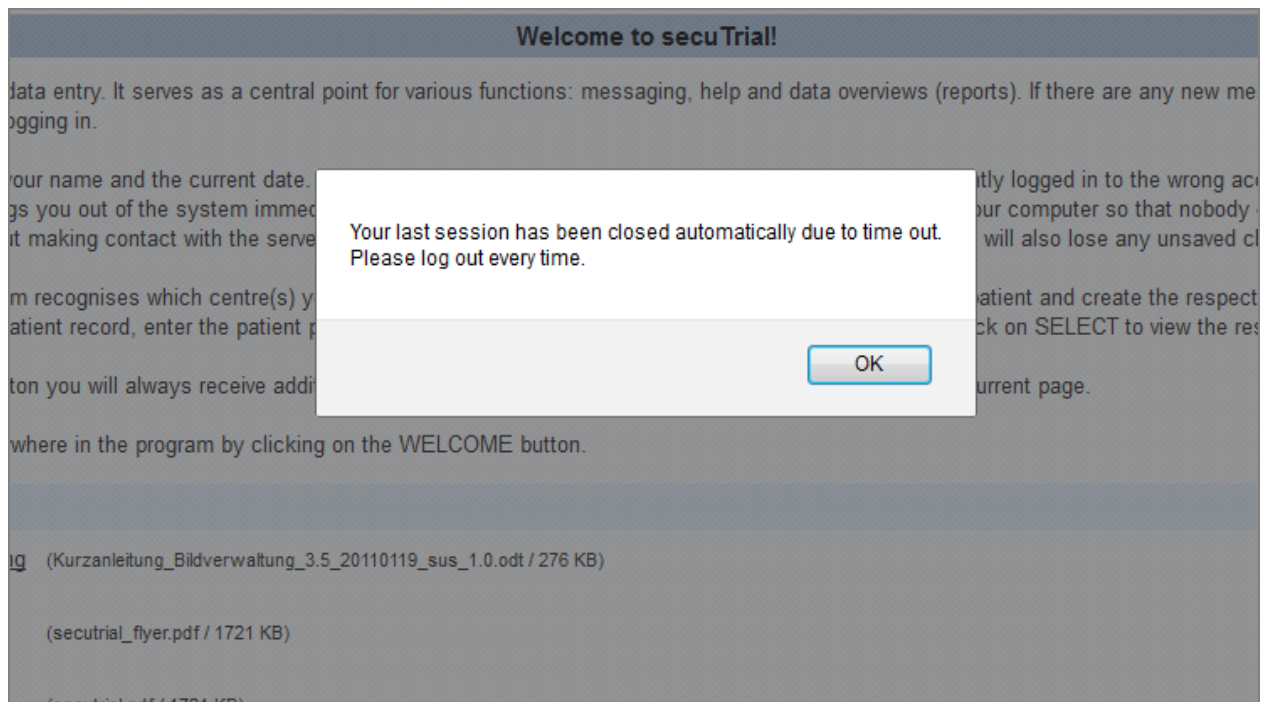


Fig. 26: Javascript message when logging in to DataCapture after the last session was ended without logging out.

On the "My Account" of the participant the time of the last DataCapture login is displayed. If there have been failed login attempts since the last login, this will be displayed as a warning next to the login time.

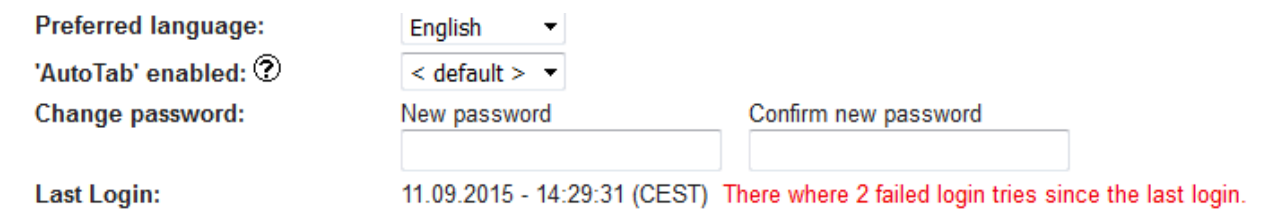


Fig. 27: Login information displayed on the "My Account" page of the participant.

As the entering of incorrect passwords is now logged in the database, failed login attempts are also counted between larger intervals of time. Before the last possible attempt (number of permitted failed attempts as configured for the customer area in the CustomerAdminTool) a warning message is therefore displayed.

For the entering of the e-signature password, however, attempts will continue to be counted per signature. Only when the permitted (=configured) number of failed attempts is exceeded multiple times consecutively will the participant be inactivated without prior warning and automatically logged out of DataCapture. If the participant (or patient) cancels the e-signature after entering an incorrect password and then opens the signature page again, the counting of attempts will be restarted from zero.

**Fixed issues**

**All tools**

#7404 A number of entries in the language XML file were duplicates or were no longer used.  
 Duplicates and unused entries have been removed from the language file.

**CustomerAdminTool**

#7650 In an inactivated customer, parts of the "Administration Tools" section could still be edited on the customer editing page.  
 This issue has been fixed.

## FormBuilder

#7809 The previous default value "-#" for flagging column-wise import of repetition groups was unnecessarily complicated.

The default value has been changed to a simple hyphen "-". Already created import formats are not affected by this change, which only applies to the creation of new import formats.

#7835, #7836 The English spelling of "catalogue" was incorrect in certain places.

The English spelling has been corrected.

## DataCapture

#7652 When a patient logs into the patient self-documentation for the first time after creating a password, the centre is normally notified with an e-mail. However, if an e-mail address had not been entered in all centres of the patient and the associated projects or in the customer, an error occurred (exception).

This issue has been fixed. If no e-mail address can be determined for sending the notification e-mail the first time that a patient logs in, no e-mail will be sent.

#7707 If patient self-documentation is used, when a password is requested by the patient and the centre is notified that the patient has logged in for the first time, e-mails are generated containing a pseudonym for identifying the patient. However, the used pseudonym was always the Pat-ID, even if the project only used the Add-ID according to the configuration in DataCapture.

This issue has been fixed. In these e-mails, a pseudonym is now always used which can also be displayed according to the project configuration and the role rights of the patient. The first displayable pseudonym is used in the order Pat-ID, Add-ID or Lab-ID.

#7781 If a patient can log in to the patient self-documentation but the patient role has not been assigned any rights to the project forms, the patient will see an error message after logging in. The content of the error message did not fully explain the problem in a suitable way (error message is also shown to participants if they try to view a patient without sufficient form rights).

The error message has been rephrased so it is more generally applicable.

## ExportSearchTool

#7786 When a design with different colour buttons (altered background colour for headings) was used in a customer area, on the page with the export lists (download, scheduled exports, export history) the clock icons were missing for exports used as planning templates and exports created as a result of a scheduled export. Instead, only the alternative texts were displayed.

This issue has been fixed.

### Error Corrections in 4.8.0

## All tools

#7827 In question components of the type IASUnitGroup or IASHorizontalUnitGroup, the default text "<Please select>" was always used for the value "NULL" in the labels of the unit pop-up, even if a different text had been entered in the item definition.

This issue has been fixed.

## FormBuilder

#7833 When creating CRF print forms, via the option on the project overview page it is possible to select whether the help texts entered in the individual questions should be displayed on the CRF. However, if this display option was selected it was ignored and the help texts were never displayed.

This issue has been fixed.

## DataCapture

#7785 In unit group question components, in addition to the unit items, other items can be defined which can also be referenced to other items or questions in the rule conditions of hide rules. However, in IAS unit group components, these hide rules could not be triggered from the same form via values in these additional items. Despite fulfilled rule conditions, the items or questions remained visible.

This issue has been fixed.

## ExportSearchTool

#7817 The CDISC export could not be successfully generated (export contains errors) if one or more patients existed in a project without every visit and in the export options the selection "first visit" had been selected as a filter.

This issue has been fixed.

### Issues fixed during development

The following issues were discovered in the development process and fixed:

#7402, #7473, #7602, #7603, #7614, #7617, #7618, #7620, #7621, #7623, #7624, #7625, #7626, #7628, #7630, #7632, #7633, #7634, #7635, #7636, #7637, #7642, #7643, #7645, #7646, #7647, #7654, #7655, #7656, #7657, #7658, #7663, #7666, #7667, #7670, #7677, #7682, #7684, #7685, #7687, #7688, #7698, #7699, #7700, #7701, #7702, #7703, #7704, #7705, #7706, #7709, #7710, #7711, #7712, #7713, #7714, #7715, #7716, #7717, #7719, #7720, #7721, #7725, #7726, #7727, #7728, #7730, #7738, #7739, #7740, #7741, #7746, #7747, #7750, #7751, #7753, #7756, #7757, #7766, #7767, #7768, #7769, #7770, #7771, #7775, #7784, #7787, #7788, #7790, #7791, #7798, #7806, #7814, #7815, #7816, #7825, #7829, #7831

## Deployment

### Database

Adaptation in the FormBuilder with the start parameter "-DSRTAdoptDB=true" is necessary.

### Configuration

**sT4.9-5, #5198, #4049, #4545**

If error page e-mails are to be sent by users and automatically in the event of errors in background functions of the CustomerAdminTool, this e-mail notification option can be set up by entering a (valid) e-mail address in the respective configuration files for the parameter "error.admin":

```
# Optional: this address will be used for sending administrative emails if any problem
# occurred during background operations (like statistic generation) or user exceptions.
# It should be valid!
#error.admin = myaddress@example.com
```

Note: If e-mail notification is only to be enabled for background tasks of the CustomerAdminTool and for when error pages are displayed within this tool, this can only be specified in the CustomerAdminTool.cfg file.

### Password file CustomerAdminTool

Due to the modified package structure of the Java classes, it is necessary to create a new password file for the CustomerAdminTool. This can be done as before via the PasswordManager with the following console command in the installation directory (usually: ST21) of the applications:

```
java -jar pwdmanager.jar
```

The necessary syntax for creating the file and adding users is generated when the command is executed.

The new login data must then be communicated to the CustomerAdminTool users using a suitable method.

# secuTrial® 4.9.0.9

Released 28/05/2015



## New Functions

### New colours for report rows #7848

For colouring rows in reports (e.g. for the purposes of highlighting) 5 new colours have been introduced that are slightly lighter than the previously available colours "yellowbg", "greenbg" and "redbg".

1	Text		if	manual freeze	is set	style	lightyellowbg	Preview	Remove
2	Text		if	review (A+B)	is set	style	middlegreenbg	Preview	Remove
3	Text		if	review (B)	is set	style	lightgreenbg	Preview	Remove
4	Text		if	review (A)	is set	style	midddleredbg	Preview	Remove
5	Text		if	empty	is set	style	lightredbg	Preview	Remove

Fig. 1: New colours for colouring reports.

## Fixed issues

### All tools

**#7846** For a bundled message dispatch, the message can be sent both as an internal message within secuTrial® and to separately entered, external e-mail addresses. When sending to additional, external e-mail addresses, the message dispatch type shown in DataCapture was not correctly displayed. The e-mail dispatch information was missing. The message was nevertheless correctly sent.

This issue has been fixed.

**#7847** In the table repetition group, the simple item label was always used as the column heading. The configuration for hiding this label and the entry in the HTML label were not taken into account.

This issue has been fixed. When the form is displayed, the same label that is used for in all other question components is now used.

**#7849** If "set password configuration" for participants was activated in a customer area, the link which was sent for creating a participant password did not lead to the create password page. Instead, it led to the customer selection page of the respective tool if patient self-documentation was also not configured for the customer.

This issue has been fixed.

## Error Corrections in 4.8.0

### All tools

**#7850** The time zone display in the status header of the tools was always shown in the installation language specified in the configuration file (German or English), regardless which language was otherwise used in the user interface.

This issue has been fixed. In certain installations the Java RE might only have one time zone name regardless of the selected language (the available names are shown in the log file when the FormBuilder is started as normal.)

## FormBuilder

#7822 In a radiobutton item the reset option can be selected and a different text can be saved for this option. This reset text was reset to the default value when the order of the reset option was changed from "at the beginning" to "at the end" (or vice-versa).

This issue has been fixed.

#7823 If multiple rules had been created in an item, the order of these orders was changed and a rule was to be deleted before saving the modified order, instead of the rule which had been selected for deletion, the rule which took the position of the selected rule after changing the order was deleted. The same error also occurred in forms within a form family, questions within a form or item, rules within a question and conditions within a rule.

This issue has been fixed.

#7851 In the current Firefox browser, when editing the layout of an item matrix it was not possible to discard the changes via the "Cancel" button (no reaction).

This issue has been fixed.

## AdminTool

#7840 When importing participants, it was not mentioned in the help text that locations entered in the import must have already been created.

The help text has been revised.

## DataCapture

#7824 When editing a patient visit plan and opening the page or displaying the preview, the cursor always jumped to the patient pseudonym selection field in the top menu bar instead of going to the editing fields on the page.

This issue has been fixed. When the visit plan editing page opens, the cursor now always appears in the first date field. When the visit plan preview is displayed, the cursor is always located in the reason field. If no preview can be created (e.g. because no change has been made), the focus is placed on the "Cancel" button.

## Deployment

No special entries required.