

# secuTrial® 5.0.3.5 – Release notes

Based on Version 5.0.2.12



## Introduction

This version introduces the facility to enter information that applies to all patients in patient-independent forms for each centre. These forms are displayed in DataCapture in a new centre form overview between the welcome level and the patient form overview. Centre forms are listed and filled out just once without repetitions, just like casenode forms.

The navigation bar has been redesigned to provide easy access to the centre view. Centres and patients can now both be called up via an extended search field.

## New Functions

Centre-specific forms

sT5.2-5.2, #8262

## Form definition (FormBuilder)

For the specification of the new form type, two new form family types have been introduced:

- Centre
- Centre subform

Any number of these two family types can be created for each project. Each centre form family is separately displayed on the centre form overview in DataCapture (see Fig. 9). Forms from centre subform families can be used in repetition groups of a centre form. These new families are listed on the project overview page underneath the patient families.

Form families (18)		
Displayed order	+ / - Form family name	Type
▶	+ <a href="#">CM Subform</a>	Subform
▶ 10	+ <a href="#">MH Subform</a>	Subform
▶ 20	+ <a href="#">Date and Time</a>	Subform
▶ 1	+ <a href="#">Eligibility Criteria</a>	Visit
▶ 2	+ <a href="#">Demographic Data</a>	Visit
▶ 3	+ <a href="#">Smoking Habits</a>	Visit
▶ 4	+ <a href="#">Alcohol</a>	Visit
▶ 5	+ <a href="#">Contraception and Pregnancy</a>	Visit
▶ 6	+ <a href="#">Treatment</a>	Visit
▶ 7	+ <a href="#">Medical History</a>	Visit
▶ 8	+ <a href="#">Physical Examination</a>	Visit
▶ 9	+ <a href="#">Vital signs</a>	Visit
▶ 10	+ <a href="#">Concomitant Medication</a>	Casenode
▶ 20	+ <a href="#">Study Termination</a>	Casenode
▶	+ <a href="#">Adverse Events</a>	Adverse Events
▶	+ <a href="#">Images</a>	Image
10	<a href="#">Centre RepGroup</a>	Centre Subform
10	<a href="#">Centre-specific Info</a>	Centre

Fig. 1: List of all form families within a project grouped according to patients (top) and centre type (bottom).

The items and rules in centre forms are created in exactly the same way as they are in normal patient forms. A number of functions are not appropriate for centre forms and therefore **cannot** be configured or selected, specifically:

- Randomization

- Messages: Inclusion of pseudonyms
- Rules:
  - Freeze / release follow-up forms
  - Freeze / delete / anonymize patient
  - Create / open AE / SAE
  - Treatment arms
- Rule conditions:
  - References to patient forms
  - Metadata: Pseudonyms / visits / AE data

It is not yet possible to configure double data entry (DDE) for centre forms. This function will be implemented in one of the next few versions.

From patient forms all centre forms can be referenced in rule conditions. During analysis in DataCapture, the form data from the currently displayed centre of the patient will be used.

When copying forms and form elements, all elements from centre forms can be copied into centre forms. It is likewise possible to copy elements from centre forms to patient forms. However, it is **not** possible to copy elements from patient forms to centre forms.

### **Setup import forms (FormBuilder)**

If you only want to import individual forms and not the entire project setup, the imported forms must be assigned to one or two (for subforms) existing families.

If the form import also contains centre forms, these must also be assigned to centre form families separately from the patient forms.

### **Centre report (FormBuilder)**

Centre forms are not listed in the normal patient reports. In order to display such information, the following new centre report types have been introduced:

- Icon display
- Status
- Query details
- Validation
- Single fields

The reports are defined in the same way as patient reports. The paper printout can also be configured for the centre query or validation report. In principle, the only difference between the printouts is that there is no patient identification.

The screenshot shows a configuration form for a report. The 'Project centres' section is highlighted with an orange border and contains the following options:

- Multiple field
- Status
- Icon display
- Query details
- Validation

Other visible fields include: 'No.' (60), 'Name' (Visit Dates), 'File name (Excel)', 'Type' (Project overview), 'Style definition of the rows' (odd/even rows), 'Ordered by' (Alphabetical), 'Help' (Show), and 'Single field' configuration (Position: 10, Form: Centre <mntpa1c>, Item: Q <cdt>, Title: Release Date, Style definition of the column: graybg).

Fig. 2: Definition of a centre single field report (highlighted: possible centre report types).

The creation of SQL or free SQL reports has not been modified for the introduction of centre forms. Centre forms are saved in the same data structure as patient forms: the form data is saved in the specified "mnp" table of the form and the metadata is saved in the "document" table of the project. Unlike patient forms, in the "document" table entry only the reference "ctrld" is related to the centre and there are no other references to the patient metatables ("cnid" to the "casenode", "cvpid" to the "casevisitplan" or "fuid" to the "followup" table).

**Note:** The reference to the centre in the "document" table is also always set in patient forms!

The assignment of rights for centre reports is performed in the AdminTool in the same way as for patient reports.

### Report display (DataCapture)

The patient and centre reports are listed in DataCapture on the report overview page in separate sections.

The screenshot displays the DataCapture interface. The header includes the following information:

- Date: 10.10.2016 - 14:34 (CEST)
- Clinical Investigator: Denny Neumann
- Project: Demo Trial (10.10.2016 - 10:22:20 (CEST))
- Time left: 59:29

Navigation links: Back | Reload | Help | Logout

The main content area is split into two columns: 'Reports' and 'Statistics'. Under 'Reports', there are two sub-sections:

- Patients:**
  - Patients Overview
  - Query Report
  - Discrepancies
  - AE Report
- Centres:**
  - Visit Dates

The 'Statistics' column shows 'No statistic to display.'

Fig. 3: List of all reports (with display rights) within a project separated into patient reports and centre reports.

In the standard reports (icon, status, single fields), instead of the patients, the centres are listed row by row. By clicking on the centre name, the centre form overview can be accessed. In certain reports (query, validation) the centre form can also be directly accessed.

<b>secuTrial®</b>	Date	10.10.2016 - 14:48 (CEST)	Close
	Clinical Investigator	Denny Neumann	
	Project	Demo Trial (10.10.2016 - 10:22:20 (CEST))	
Reload   Excel   Print			
Visit Dates			
Centre	Centre-Info		
	Release Date		
Centre A	11.11.2011		
Centre B			
Centre C	12.12.2012		

Fig. 4: Example centre report.

### Configuration of DEC and SDV per form (FormBuilder)

In previous versions, the two workflows for data entry complete (DEC) and source data verification (SDV) could only be activated or deactivated per project. To enable a clear distinction between patient and centre forms within a project, the configuration for these two workflows has also been refined.

Within a project, these two workflows can now be set to

- never
- always
- scalable

If "scalable" is selected, the workflows can then be additionally selected per form.

<b>Version:</b>	<b>Development</b>	<b>Release:</b>	<b>By:</b>
<b>Vers. label:</b>	<input type="text"/>	<b>Vers. no.:</b> 2	<b>Last vers. modification:</b> 10.10.2016 - 10:22:20 (CEST)
<b>Project name: *</b>	<input type="text" value="Demo Trial"/>		
<b>Extended features:</b>	<div style="border: 1px solid orange; padding: 2px;">                 Source Data Verification (SDV)    <input type="radio"/> never    <input type="radio"/> always    <input checked="" type="radio"/> scalable                  Data Entry Complete (DEC)    <input checked="" type="radio"/> never    <input type="radio"/> always    <input type="radio"/> scalable             </div> Discrepancies Transfer Module (DTM) <input type="checkbox"/> Patient Reported Outcome (PRO) <input type="checkbox"/> Double Data Entry (DDE) <input type="checkbox"/> ? Centre Specific Project Versioning (CPV) <input type="checkbox"/> ? Patient deletion (productive area) <input checked="" type="checkbox"/> ?		

Fig. 5: Configuration of extended functions in a project: introduction of the new option "scalable" for SDV and DEC.

<b>Form name (overview): *</b>	<input type="text" value="Demographic Data"/>
	<input checked="" type="radio"/> user input <input type="radio"/> display only <input checked="" type="checkbox"/> save <input type="checkbox"/> print <input type="checkbox"/> E-Signature
<b>Processing: *</b>	<div style="border: 1px solid orange; padding: 2px;"> <input checked="" type="checkbox"/> Data Entry Complete (DEC)    <input checked="" type="checkbox"/> Source Data Verification (SDV)                 </div>
<b>Database table: *</b>	mnpa1 <input type="text" value="dm"/>

Fig. 6: Configuration of DEC and SDV as processing options within the form.

When assigning form rights in the AdminTool, the associated form rights can now only be assigned to forms which have the respective workflow activated.

In DataCapture the SDV and DEC workflows are likewise only available for these forms.

### Import configuration (FormBuilder)

Imports are also possible for centre forms. Apart from mass imports (this import type is irrelevant for imports to centre forms), all import types can be used.

When creating import configurations in the project, it must be specified whether the configuration is intended for a multi-mass import in patient forms (all previous configurations) or centre forms.

Identifier: *	CC1
Description:	Centre 1 import
Form type:	<input type="radio"/> Patient related <input checked="" type="radio"/> Centre related
Centre: *	cc1

Fig. 7: Specification of the form type in the import configuration of a project.

When defining an import format for an individual centre form, information identifying the dataset and the visits is not necessary and is not provided.

### Extended navigation bar (DataCapture)

In order to provide access to the centre form overview, the search window in the navigation bar has been revised and extended. As soon as two letters are entered, all centres with centre forms and all patient pseudonyms containing the entered letters are searched for and listed. Capitals and lower case letters are ignored in the search. The matches are listed separately according to type and project.

The screenshot shows the secuTrial DataCapture interface. At the top, the user's name 'Dipl. Biol. Susanne Schneider' and the date '16.11.2016 - 13:04 (CET)' are displayed. A navigation bar contains links for 'Welcome', 'Icon-Darstellung', 'My Account', 'Messages', 'Mass Action', 'Import', 'Reports', and 'New patient'. The main content area displays a 'Welcome to secuTrial!' message and instructions for data entry. On the right side, a search dropdown menu is open, showing results for the search term 'BO'. The results are categorized into 'Centre' (Bonn (Beispiel-Projekt)) and 'Patients' (BO-001, BO-024, BO-317).

Fig. 8: Example search for "BO": both the centre "Bonn" and the patients with the prefix "BO" in the Add-ID are found and listed.

During the search, all access and display rights are taken into account, e.g. centres are only included in the search if a minimum of one centre form exists that the current participant is at least authorised to display. When searching for pseudonyms, the display rights for the various pseudonyms are also taken into account. If a participant is authorised all or multiple pseudonyms of a patient, the pseudonym is listed with the search matches.

The participant can then select a match from the list or enter further letters. After each additional letter is entered, the search is accordingly refined.

### Centre form overview (DataCapture)

In accordance with the patient form overview, in DataCapture there is now a new page showing all centre forms of a centre. In this overview all centre form families are listed in separate sections. The family name is used for the tab label and all forms are listed below it one after the other.

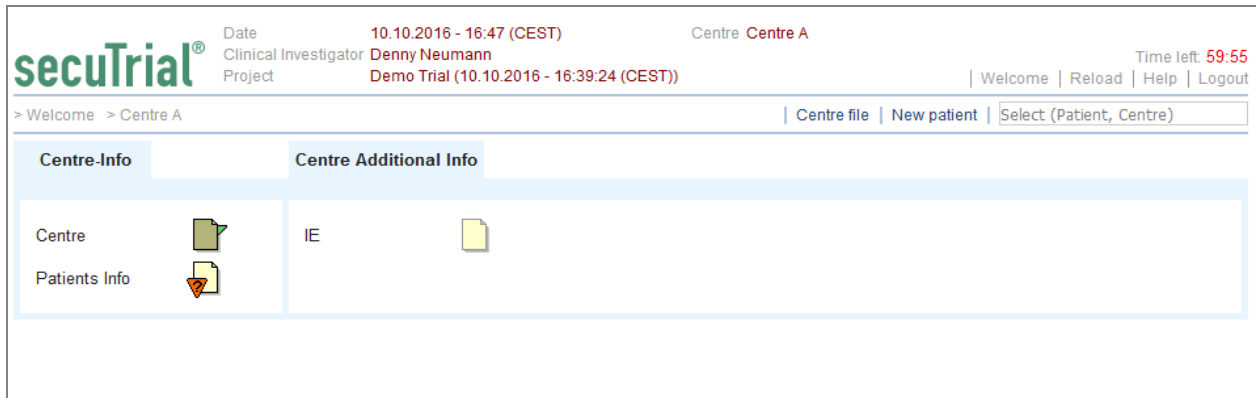


Fig. 9: Centre overview - shown here with three families and different forms and editing statuses.

Centre forms are only ever filled out once per centre. No visits or events are repeated. If repetitions need to be entered, this can be done in repetition groups within a form.

The individual form can then be opened for data entry by clicking on the icon or name. All normal form functions and workflows can then be used in accordance with the project and form configuration and the rights of the current participant. These include:

- Missing Values (MV)
- Source Data Verification (SDV)
- Data Entry Complete (DEC)
- Queries
- Comments
- Review
- Freeze

### Centre file (DataCapture)

Similar to creating the patient file, on the centre form overview a centre file can also be created with all centre forms or selected centre forms. As an additional option, all centres of the project to which the current participant is assigned can also be included in the centre file. Per centre one HTML file or PDF file is always created; all created files are bundled in a ZIP file for download.

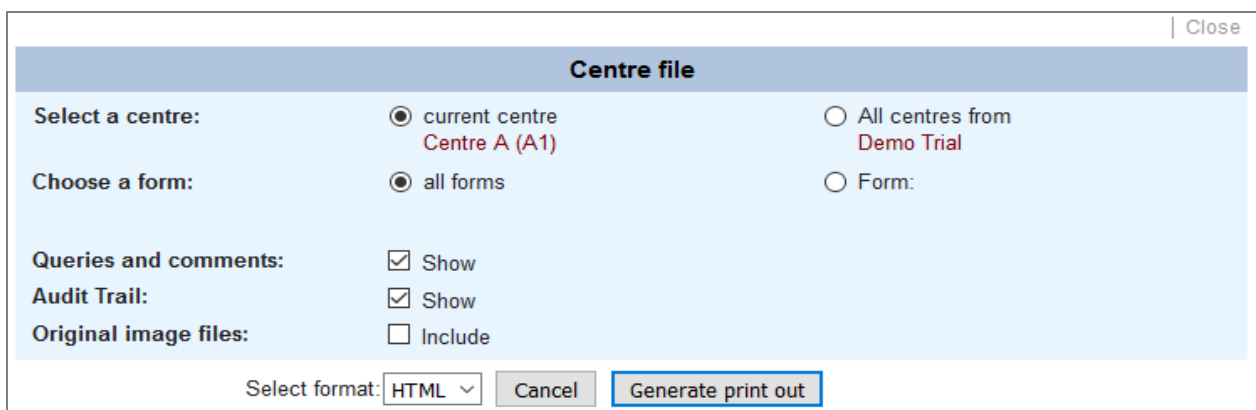


Fig. 10: Pop-up window for creating the centre file.

### Adjustment of the navigation bar in the patient (DataCapture)

If centre forms have been defined in the project and if the current participant at least has display rights for a centre form, a "centre" link will be displayed instead of the "welcome" link in the general menu bar of the patient form overview. The name of the centre will be added to the breadcrumb trail between "Welcome" and "Patient". Both centre links lead to the form overview of the centre.

### Unfreezing centre forms (AdminTool)

To enable frozen forms to be opened once again in DataCapture, the centre editing page has been extended in the AdminTool. If there is at least one frozen form in a centre, an "Unfreeze" button will be displayed on the editing page of the centre.

The screenshot shows a form for editing a centre. Fields include Name (Centre A), Email (denny.neumann@interactive-systems.de), Maximum number of patients, Already recruited patients (5/29), Type (Study centre selected), Location, Country, and Project (Demo Trial (A1)). At the bottom, the 'Unfreeze forms:' label and button are highlighted with an orange rectangle.

Fig. 11: Excerpt from the editing page of a centre with frozen centre forms (highlighted).

All frozen forms will then be listed on the unfreeze page. The forms can be selected and then unfrozen by entering the login data of an authorised participant. The participant must be active, assigned to the centre and have the "freeze" right for the frozen forms. Furthermore, data entry for the project must not have been closed in the AdminTool.

The screenshot shows the 'AdminTool: Unfreeze forms' page. It displays a list of forms for 'Centre A (A1)'. A 'Notice' states: 'To unfreeze these forms please log in with a valid participant account for this centre.' Below the notice are input fields for 'User-ID' and 'Password', and an 'Unfreeze' button. A 'Cancel' button is also visible at the bottom left.

Fig. 12: Page for unfreezing centre forms. All frozen forms are listed. If necessary, the meaning of the e-signature is stated.

If unfreezing was not possible either wholly or in part, e.g. because the dataset is currently being edited in DataCapture, a list of forms that were unable to be unfrozen will be displayed as the outcome of this action.

### Deletion of centres (AdminTool)

The deletion of centres can be enabled for a customer area in the CustomerAdminTool. Then all centres can be deleted which do not have any patients or participants assigned to them and in which no patient has ever been created or assigned.

A centre can no longer be deleted if at least one saved centre form exists for the centre.

### Export

Centre forms can be exported with export formats with the exception of the rectangular format. All options and filters (if suitable) can otherwise also be applied to centre forms.

In the form tables for centre forms, the centre database ID (mnpctrId) is used instead of the patient database ID (mnpPid). In these tables, all columns containing patient information are removed. If metadata is repeated, only the centre name is repeated in these form tables.

In all tables that can contain information about different form tables, e.g. queries or SDV, both the patient and the centre columns are included if such forms exist in the project setup.

In the CDISC format, the centre forms are defined per family as a separate "StudyEvent". The form contents are then exported in the "StudyData" section and the centres are used as the "Subject". For the element IDs, the prefix "CTR" is used for centres to avoid confusion with identical database IDs in different objects (patients / centres).

A precise description of the respective table structures can be found in the export format documentation.

## Miscellaneous

### No character encoding options for HTML/PDF downloads

**#8778**

In previous versions, in all tools it was possible to select the required character encoding for downloads in HTML or PDF format. However, unlike the CSV format, in these file formats the used character encoding can be written into the file.

Therefore, the universal standard character encoding UTF-8 is used for these formats and a selection is no longer made by the user.

## Fixed issues

### CustomerAdminTool

#8929 A selection list of all languages configured in the installation was offered for downloading the database documentation, even though the documentation is only available in German and English (English documentation is used for all languages apart from German).

The choice of languages has been limited to German and English.

### FormBuilder

#8930 When creating a new table repetition group, normal subforms were also offered in the selection list of possible subforms. Only when saving were only subforms with the "Tables" configuration accepted.

This issue has been fixed. The choice of possible subforms is already filtered when selecting the repetition group component type.

#8951 When defining the "Freeze single form" or "Release single form" rule, the form which is to be frozen or released must be selected in the rule definition. In the list of forms, forms without a database table were also offered, even though they cannot be frozen.

This issue has been fixed. The selection list now only contains forms with a database table. If non-saveable forms have already been specified in such a rule (despite the fact that such a rule would have no effect), the selection must be corrected the next time the rule is edited.

#8985 In the print view of the editing page for import formats, the mass import configuration documentation was missing.

This issue has been fixed.

#8993 If a query report has been created with the function "paper print" and this report had been changed into another report type the print function was still listed after the report type in the report overview list.

The issue has been fixed. If a report type with print-function is changed into another type where this function is not supported the print function will be reset.

### AdminTool

#8924 When sending reminder message for empty visits, in certain cases out-of-memory errors occurred.

The implementation for dispatching visit reminder message has been optimised.



## DataCapture

#8260 The interim page with the save message and for entering the e-signature is now displayed on an overlay on top of the form. If a "Freeze follow-up forms" or "Release follow-up forms" rule is fulfilled on the edited form and this action requires an e-signature, all of the follow-up forms are listed on the overlay. If the form was very short or listed a large number of follow-up forms, in some cases the entire overlay was not visible. In the worst-case scenario, the function elements in the overlay (selection of the next action) could no longer be used.

This issue has been fixed. The overlay is always fully displayed, regardless of the form size. If a large number of follow-up are listed in the overlay, this form list is separately scrollable in the overlay.

#8925 If a table repetition group was defined in a form and the used subform did not contain a single question, the form could not be opened, edited or printed (exception).

This issue has been fixed. Table repetition groups without a single question in the used subform are listed as an error during project validation.

### Issues fixed in 5.0.2

## FormBuilder

#8915 When defining messages in a subform item, it is also possible to add questions from the main form within which the subform was created. However, as the source for these questions it was only possible to select "first" and "last" visit for visit forms.

This issue has been fixed. It is now also possible to select "current" and "previous" visit for visit forms. If the subform with this message is also used in a casenode form, although the selected question and item texts are included in the message if the rule condition is fulfilled in this form, no item values can be included (when sending from the casenode there is no "current" visit).

#8959 When importing project setups from previous versions, error messages were listed in the log file regarding "importmappings" and "customerschemas", but they had no effect on the performed import.

This issue has been fixed. In the log file only a warning is displayed now (due to renaming in the data model).

#8963 When copying rules all rule conditions were deleted that compared a metadata value instead of an item value.

This issue has been fixed.

## AdminTool

#8914 If the column heading were accidentally included in the analysis for the patient import, the column names used in the error message were not the same as in the import help.

The error message is now the same as the help text.

#8916 In the online help for the patient import, an explanation was missing regarding the formats available for importing the patient visit plan.

The help text has been extended.

## DataCapture

#8918 When editing the adverse event data for a patient (change from form overview) a reason must be entered. If a reason was not entered, the change was not saved and an error message was displayed. However, the text field for entering the reason was not displayed.

This issue has been fixed.

#8961 It was not possible to import discrepancies, after analysis an error (exception) occurred.

This issue has been fixed.

## Issues fixed in 5.0.1

### FormBuilder

#8934 If modified report fields from casenode forms existed in a single field per visit report, the project version comparison could not be performed (exception).

This issue has been fixed.

#8875 If a whole project setup with DDE configuration and DDE forms was imported into a project where no DDE function had been previously configured a message was displayed erroneously after upload that the DDE function had been reset. Nevertheless the project setup was correctly imported with DDE configuration and forms.

The issue has been fixed.

### DataCapture

#8917 In the status report it is possible to configure the additional display of summarised statuses per column and centre. In the downloaded Excel field of the report, only the summarised status for the first listed status (first row of the sum) was correctly displayed. All other summarised statuses were not displayed.

This issue has been fixed.

#8923 If the uploaded image was changed in an image item in the form, both the old and the new file were displayed in the audit trail as thumbnails (if the image files were able to be displayed as thumbnails). In the downloaded patient file, these thumbnails were missing in the audit trail in PDF format. If the original images were included with the patient file, it was nevertheless possible to download the original file by clicking on the place where the thumbnail should have been.

This issue has been fixed. Any already existing faulty patient files must be newly created.

#8957 When defining an SDV reset message in the project, it is possible to specify that the affected SDV items should be included in the message. However, instead of just the items with reset SDV, all items that had not been modified were sent with the message.

This issue has been fixed. (This was a subsequent error resulting from the change in SDV treatment in 5.0.1.)

### ExportSearchTool

#8877 During export of projects with configurable randomization the random number and group are included into the casenode table as separate columns. In the SAS and SPSS format these columns are labeled by the label of the corresponding randomization item with appended "no" for the random number and "group" for the random group. These extensions were appended without any separating space or character.

The labels have been optimized. The number label is now extended with " (no)", the group label with " (group)", each separated by a space from the defined item label.

## Issues fixed in 4.9.1

#8920 In a single field or single field per visit report, for items with numeric values it is possible to set limit values from which another style sheet should be used for display in the report. However, when the report was downloaded as an Excel file, the exceeding of this limit value was not highlighted with a different font.

This issue has been fixed. Exceeded limit values are now highlighted with red text in the Excel file.

## Issues fixed during development

#8831, #8879, #8890, #8894, #8895, #8896, #8898, #8900, #8919, #8922, #8927, #8928, #8936, #8937, #8938, #8939, #8940, #8943, #8945, #8947, #8948, #8949, #8952, #8953, #8954, #8955, #8956, #8958, #8960, #8962, #8964, #8966, #8968, #8969, #8971, #8981, #8984, #8982, #8989, #8991, #8992, #8994

## Deployment

### Database

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



# secuTrial® 5.0.3.8 (incl. 5.0.3.6-7) – Release notes



## New Functions

### New Functions of 5.0.1

#### List import into hierarchical lookup tables

**#8386, #9034, #8385**

It is already possible in the FormBuilder to import CSV list files into a lookup table to create or update table entries. If multiple value columns were included in the import file then new tables had been created and the values were imported into that new, appropriate hierarchical linked tables.

This handling has been changed. Now if the import of a multiple-column file is made into the upper table of already hierarchical linked tables the lower columns are imported into the existing, lower lookup tables. Only if there are no lower tables, they will be created new as before.

## Fixed Issues

### AdminTool

#9033 If the first line with headlines is erroneously analyzed, an error message is displayed because the headline of the entry date cannot be transferred into a date. Instead of the label for the entry date the error message contained an untranslated entry from the language file.

The issue has been fixed.

### DataCapture

#8970 In the new, extended search field the found objects are listed separately according to centre and patient. The formatting of the subtitles in the search result on the form overview page differed from the display on the welcome page.

The formatting has been unified.

#9032 All images and files that had been uploaded in image items in secuTrial® version prior to 5.0.3.5 were no longer found. These files were displayed as "missing" in the form display, audit trail and export. This error occurred although all files were still existing on the server.

The issue has been fixed. It was caused by a change in the path calculation to the files in the file system of the server. This change has been revoked.

**Important:** For complete correction of this error all files that have been uploaded in the secuTrial® version 5.0.3.5 must be moved in the file system (see: Deployment)

#9041 It is possible to include data from the current form into form and rule messages. In messages on casenode or adverse event forms only the question and item labels were included but not the values entered into the form. Only the content of form messages from visit forms were correct.

The issue has been fixed.

#9042 On the report overview page the projects are sorted alphabetically by name. In contrast to all other sortings in secuTrial® the sorting was case sensitive.

The sorting of projects by name is now done alphabetical and case insensitive.

## Fixed Issues of 5.0.2

### DataCapture

#8889 A form could not be saved (exception), if the SDV function was configured in the project and a hide-rule was configured on an item in a repetition group that used a meta data in the rule condition.

The issue has been fixed.

#9024 If a participant clicks on the "password forgotten" button and the participant has no e-mail stored, a note is displayed that the participant has to contact the participant administration for a new password. This note contained a spelling error in the German version.

The German spelling has been corrected.

## Fixed Issues o 5.0.1

### All Tools

#8935 Before setting an item to productive mode the item type can be changed arbitrarily into any other type. When changing the data type of an item secuTrial® tries to contain as much test data as possible. When a text or number item had been changed into a date or time item and test data had previously been entered into the form it could happen that the form was no longer displayable or exportable (exception). In order to solve the problem the causing item had to be deleted and recreated.

The issue has been fixed. When other data type items are changed into a date or time item all test data will now be deleted completely.

### FormBuilder

#9025 If a report of the type single field or single field per visit contained more than 255 columns the excel download could no longer be generated (exception).

The issue has been fixed. If there are more than 255 columns the excel download will now be created in the Excel 2007 format. This newer format allows distinctly more than the 255 column of the Excel 97 format. The new file version is characterized by the ending ".xlsx".

#9035 When creating a new, simple lookup table another simple table can be selected as the upper table for a hierarchical linkage. In the selection list only the lookup description text was displayed. This could be ambiguous because this description is not necessarily unique.

In the selection list the table name is now also displayed.

#9036 After uploading a CSV list into a lookup table a page is displayed with the analysis result. On top of the page is a link to the Welcome page. When clicking on this link an error (exception) occurred.

The issue has been fixed.

#9038 When a new lookup table had been created after an extended lookup table has been edited or deleted the new table was created without a visible selection of either the properties "extended" or "simple". The new table was nevertheless internally handled as "simple".

The issue has been fixed.

#9039 When importing entries into simple lookup tables new, hierarchical linked tables were created if necessary. The table names for the new tables were automatically generated by appending the level number to the table name of the import-start table. If the generated table name was already used by an existing lookup table the import could not be performed.

The issue has been fixed. When generating the new table name the names will be counted up until an unused name could be created.

#9043 When opening the popup window displaying the rule references it could happen that an error (excpetion) occurred and the references could not be displayed.

The issue has been fixed.

#9044 The initial selection of "simple" property of a new created lookup table could not be changed to "extended" (exception, aftereffect of #9038).

The issue has been fixed.

## DataCapture

#8972 The sequence of entries in the downloaded excel file of the validation report did not correspond to the sequence in the online display if the sorting of the online report has been changed prior to the download.

The issue has been fixed.

## Deployment

### File system

**#9032**

To complete the bugfix for the display of uploaded files some directories in the resource directory of the installation have to be renamed. This only applies to files uploaded in the secuTrial® version 5.0.3.5. These files are included in subdirectories in the following directories:

```
[installation shortname]/setup/patientimages/[customer DB prefix]/[project DB scheme]
[installation shortname]/productive/patientimages/[customer DB prefix]/[project DB scheme]
```

In these directories are further sub-directories which are named according to the following patterns:

- 1) number/number/..
- 2) "centreimages"+number/number/..
- 3) "patientimages"+number/number/..

The patterns 1) and 2) shall be unchanged.

The directories with the name pattern 3) has to be renamed by removing the part "patientimages" and maintaining the number part. If there is already a directory with that number the directories have to be merged (by moving the sub-directories from the "patientimages" into the corresponding number directory).

#### Example before:

```
ST21/productive/patientimages/IAS/IAS0/3/13/13/bild1.jpg
                               /5/25/125/datei2.pdf
                               /patientimages3/13/13/bild2.png
                               /patientimages7/37/137/datei3.pdf
                               /centreimages2/12/12/datei1.pdf
```

#### Example after:

```
ST21/productive/patientimages/IAS/IAS0/3/13/13/bild1.jpg
                               /bild2.png
                               /5/25/125/datei2.pdf
                               /7/37/137/datei3.pdf
                               /centreimages2/12/12/datei1.pdf
```

For installations on an Unix system the separate script

```
find_wrong_pathnames.sh
```

will do that renaming. At the beginning of the script the path to the root resource directory of the installation has to be adjusted, the shortname "ST21" may have to be replaced by the used installation shortname:

```
# MUST BE SET SUITABLE TO THE SYSTEM!
ST_DATA_DIR=/var/WebObjects/ST21
```

The execution of the script has to be done as `root`. The script will first list all directories which can be renamed without conflicts, executes the renaming and lists the to-be-merged directories afterwards and will perform the merge at last.

**Note:** This adjustment is only necessary, if the secuTrial® version 5.0.3.5 has really been used!





# secuTrial® 5.0.3.9 – Release notes



## New Functions

No new functions implemented.

## Fixed Issues

### FormBuilder

#8629 When trying to save a new-created report of the type single field without a selected item an error message was displayed. That error message consisted of an untranslated entry from the language file.

A correct error message is now displayed.

### DataCapture

#9027 When the form overview of a patient was shown and the patient was included into multiple projects (register and part projects) and the patient's pseudonym was entered again into the search field an error occurred (exception).

The issue has been fixed.

#9051 Patients that were included into multiple centres or projects were listed multiple times in the result list of the search field.

The issue has been fixed.

#9056 It is possible to configure the e-signature for entering a query or comment. If only a limited amount of login-tries were allowed and the entered e-signature data (login or password) was wrong an error occurred (exception) and the participant was neither inactivated nor automatically logged out (as done after incorrect e-signature on the main form).

The issue has been fixed. After multiple incorrect entries of the e-signature data in comment or query the participant will now be automatically inactivated and logged out from DataCapture.

#9065 The import of CSV data into a visit or adverse event form of a patient was not possible if the import was performed from the opened form (single form import). After analysis no data was found in the import.

The issue has been fixed.

## Deployment

No special handling necessary.



# secuTrial® 5.0.3.11 (incl. 5.0.3.10) – Release notes



## New Functions

No new functions implemented.

## Fixed Issues

### CustomerAdminTool

#9064 The archiving of a project, that had been created in secuTrial® version previous to 5.0.3 and in which the functions DEC or SDV had never been activated, failed with an exception.

The issue has been fixed.

### AdminTool

#9113 An unused role could no longer be deleted. Clicking on the displayed "Delete" button only removed the button.

The issue has been fixed.

### DataCapture

#9067 If a user enters the wrong login data for the e-signature the user will be inactivated and automatically logged out. The behaviour of the application differed if the logout was performed from the main page (during signing a form) or from a popup browser window (during signing a query or comment): In the main window the logout page was displayed with an descriptive error message, from the popup window only the login page was shown without any additional information.

The issue has been fixed. Even when logged out from a popup the logout page is shown with an descriptive error message.

#9072 If secuTrial® had been installed with a second proxy webserver and both webserver used different protocol types (HTTP and HTTPS), the search field for displaying patients or centre forms could not be used. After entering a complete or partly pseudonym or centre name only the error message "The results could not be loaded." was displayed.

The issue has been fixed.

#9083 Imported discrepancies can be transferred into queries. It is configurable that the creation of a query requires the e-signature. If the user entered wrong login data multiple times for the e-signature an exception occurred. The user was not inactivated or logged out automatically although that should have happened.

The issue has been fixed.

#9085 During the DDE comparison for a single patient the patient's pseudonym was not displayed in the title of the window when saving the comparison for equal forms.

The issue has been fixed.

#9086 In the window for the DDE comparison for a complete project or a single patient in some steps the old layout style was used for the upper status and menu part of the page.

The layout has been upgraded.

#9103 If a patient was viewing the form overview of his data within the Patient Reported Outcome function the search field for the patient and centre forms was displayed. The patient could use this to search for other patients data and view or edit the other patient's data.

The issue has been fixed.

#9130 During the subsequent editing of a patient's visit plan a thin black line was displayed below the editing area.

The layout has been corrected.

#### Fixed Issues from 5.0.1

#### **DataCapture**

#9137 After an Adverse Event has been transferred into a Serious Adverse Event by rule the form overview will show even all SAE-marked forms for that event. When a new follow-up had been created for such an event not the first AE form was opened as specified by the sequence in the AE family but the first SAE form. Only after the SAE form was saved the other AE forms could be edited as well.

The issue has been fixed.

#### **Deployment**

No special handling necessary.