

# secuTrial® 5.1.0.20 – Release notes

Based on Version 5.0.3.11



## Introduction

This version contains a new report type that displays the development of values within a patient as a chart. Within forms, values from other forms of the patient can be displayed as non-editable and non-saveable additional information.

The following new functions have been introduced:

### Extended project setup

- 1. Value development charts Page 1
  - Report definition (FB)
  - Assignment of rights (AT)
  - Display in the patient (DC)
  - Chart examples
- 2. New rule "Display value from ..." Page 7
  - Rule definition (FB)
  - Display in form (DC)
  - Patient file (DC)
- 3. Options for displaying the audit trail Page 9
  - Configuration in the project (FB)
  - Display in form (DC)
  - Display in the patient file (DC)
- 4. Delete confirmation for repetition group Page 10
  - Configuration per question (FB)
  - Form display (DC)

### Miscellaneous

- 5. Revert project setup to productive version (FB) Page 11
- 6. Calculation of the sum status icon (DC) Page 13
- 7. "Event" column in the discrepancies report (DC) Page 13
- 8. Displaying rule references in all project versions (FB) Page 13
- 9. Pre-selection of project when creating new centres (AT) Page 14
- 10. Sorting of roles for resource editing (AT) Page 14

*(CAT=CustomerAdminTool, AT=AdminTool, FB=FormBuilder, DC=DataCapture, EST=ExportSearchTool)*

## New Functions

Extended FormEngine options

- 1. Value development charts sT5.1-1, #6256, #8388, #8478

Certain measured values are easier to analyse in chart form. A new "Value development" report type has therefore been introduced in secuTrial® which enables pre-defined values in the report to be displayed as a chart per patient.

### Report definition (FB)

The "Value development" report can be created as a new report type for individual patient reports (new report category).

Type *	Project overview <input type="radio"/> SQL ? <input type="radio"/> free SQL ? <input type="radio"/> Single field <input type="radio"/> Single field per visit <input type="radio"/> Status <input type="radio"/> Icon display <input type="radio"/> Query details <input type="radio"/> Validation <input type="radio"/> Image forms Project centres <input type="radio"/> Multiple field <input type="radio"/> Status <input type="radio"/> Icon display <input type="radio"/> Query details <input type="radio"/> Validation <b>Single patient</b> <input checked="" type="radio"/> Course of values Course on * <input type="text" value="Visit plan overview + single visits"/> Disposition * <input checked="" type="radio"/> chronological <input type="radio"/> sequential ? Image size * <input type="text" value="normal (default, 600x400 pixels)"/> Chart type * <input type="text" value="line chart"/> Label x-axis <input type="text"/> Label y-axis <input type="text" value="Kg"/>
Help	<input type="checkbox"/> Show
Item	Position* <input type="text" value="20"/> ? Form* <input type="text" value="General examination &lt;mnpias0image1&gt;"/> Item* <input type="text" value="Subsequent examinations - Weight &lt;zahl3&gt;"/> Repetition group * <input type="text" value="100 - Course of weight"/> Date / time of measurement <input type="text" value="Subsequent examinations - Date of weighing &lt;dtw&gt;"/> Repetition group * <input type="text" value="100 - Course of weight"/> Use as marker <input type="checkbox"/> Title <input type="text" value="Weight"/> Label y-axis <input type="text" value="&lt; Main y-axis &gt;"/> or <input type="button" value="Add y-axis"/> Colour (dots / line / bar)* <input type="text" value="# 0033FF"/> <input type="button" value="Preview"/> <input type="button" value="Remove"/>
Item	Position* <input type="text" value="30"/> ? Form* <input type="text" value="General examination &lt;mnpias0image1&gt;"/> Item* <input type="text" value="Subsequent examinations - Diet done? &lt;popup&gt;"/> Repetition group * <input type="text" value="100 - Course of weight"/> Date / time of measurement <input type="text" value="Subsequent examinations - Diet start &lt;subd&gt;"/> Repetition group * <input type="text" value="100 - Course of weight"/> Use as marker <input checked="" type="checkbox"/> End date / time of marker <input type="text" value="Subsequent examinations - Diet end &lt;subd2&gt;"/> Repetition group * <input type="text" value="100 - Course of weight"/> Value from which marker is "on" * <input type="text" value="1"/> Value up to which marker is "on" * <input type="text" value="1"/> View marker as <input type="text" value="Area"/> Title <input type="text" value="Diet"/> Label y-axis <input type="text" value="&lt; Main y-axis &gt;"/> or <input type="button" value="Add y-axis"/> Colour (dots / line / bar)* <input type="text" value="# 33FF66"/> <input type="button" value="Preview"/> <input type="button" value="Remove"/> <input type="button" value="New item"/>

Fig. 1: Definition of a "Value development" report (selected report type highlighted) in FormBuilder.

For the "Courses of development" report the following must be selected:

1. Course on

Only events of the same type can be displayed together in a chart, i.e. visits, adverse events or casenode forms. You can select whether a general overview and / or the individual events should be displayed in the chart. The following options are available:

- Visit plan overview
- Visit plan overview + single visits
- Adverse events overview
- Adverse events overview + single adverse events
- Single adverse events
- Patient (casenode forms)
- Image form overview
- Single image forms + single image forms

## 2. Disposition

Specifies the X axis for presenting the development of a value in the chart. Chronological presentation shows the proportional development over time on the X axis without labelling the events. Sequential presentation shows the order of the events labelled on the X axis without any indication of timescale.

## 3. Image size

If there are only a few data points, a small image is perhaps sufficient. For lots of values, a larger image might be helpful. Three options are available:

- small (300x200 pixels)
- normal (default, 600x400 pixels)
- large (900x600 pixels)

## 4. Chart type

Selects the type of graphic representation. The following options are available:

- Bar chart
- Line chart
- Scatter chart

## 5. Label X axis / Y axis

For both axes any text (max. 100 characters) can be entered as a label.

Depending on the chosen report type, one or more items can be selected from the respective form families for display. You can select numeric items, radiobutton/pop-up items and date/time items. For each item the following information must be entered:

### 1. Position

Used for the order of the items in the chart legend and for report editing and project version comparisons. Automatically rounded up in increments of 10 when a new item is added.

### 2. Form

Depending on the "value development" report type, the forms from the corresponding form family type are offered here.

### 3. Item

Items can be selected from the main form and from all contained subforms. If you select a subform item, the respective repetition group must also be selected to ensure unambiguous identification.

### 4. Date / time of measurement (optional)

Option only available if chronological presentation has been selected. With chronological presentation, the date of the associated visit/examination date of the AEs is used as the time of measurement. In the case of image forms, the form creation date is used. If required, a different item can be set as the date for the value (=point on the X axis). If a subform item has been selected as the value, it is only possible to select a date item from the same subform in the same repetition group. If incomplete information is entered (e.g. month and year in a day-month-year item), the missing information is filled with the respective start value (01.01. of the year or 00:00:00 for the time).

**Important:** If no measurement date or time exists for a measurement value, e.g. because no information has been entered in the selected date item, the measurement value will not be displayed in the chart! In the case of two measurement values (from the same item) taken at the same time, only the last value (in the order of the forms) will be displayed.

### 5. Use as marker (optional)

Instead of displaying the item as an actual value, you can use this option to display the item as a marker (on / off) for a certain condition. The condition is defined via the value limits in the item (see below).

6. End date/time of the marker (optional)

If chronological presentation is selected and the item used as a marker with an item selected as the source for the measurement date/time, an item can then also be selected as the end date/time. For example, this can be used to mark the duration of a performed treatment in chart. Again, it is only possible to select a date item from the same form and the same repetition group from which the item was selected.

7. Value from which marker is "on" / Value up to which marker is "on" (required for marker)

Selects the condition which determines that the item value is displayed as "on". *Example:* Blood pressure is measured in a numeric item. Instead of displaying blood pressure as values in the chart, it should only be marked if it is higher than 150. In this case, the first value would be (on from) "150" and a higher number would be entered as the second value (on up to), e.g. "300". If using radio buttons as markers, the check for the option can be defined so that the same DB value is entered for "from" and "up to".

8. Title (optional)

The name of the (max. 40 characters) of the displayed value or marker which is to be used in the chart legend.

9. Label Y axis (optional)

You can select whether the main Y axis is to be used as the representation for all items (all values will then be entered on the same scale) or whether other Y axes are to be added for one or more of the displayed values. An additional axis is added as text (max. 100 characters); if the texts are the same they are treated as being the same axis. When displaying date and number items as values in the same chart, at least two axes must be specified. Multiple items can use the same additional Y axis (selection from the list). Axes that are no longer used are deleted from list upon saving.

10. Colour (dots / line / bar)

The colour for depicting the item as dots, lines or bars must be specified here as a hexadecimal entry in the format RGB (= red/green/blue). A palette pop-up helps you to select a suitable colour. The selected colour is displayed as a preview.

Incorrect entries in the definition of the value development report are marked with an error message directly next to the respective property.

**Assignment of rights (AT)**

The assignment of rights for the new value charts is done in the same as for other report types in the AdminTool under "Resources".

**Display in the patient (DC)**

The new value development reports are not listed on the report overview of the welcome page. Instead, a new menu button can be found in the form overview for a selected patient. If the participant has the right to at least one value development report of the current project in his or her role, clicking on this button will open an additional report window (see Fig. 2). The same menu button is also displayed in the open form (see Fig. 3).

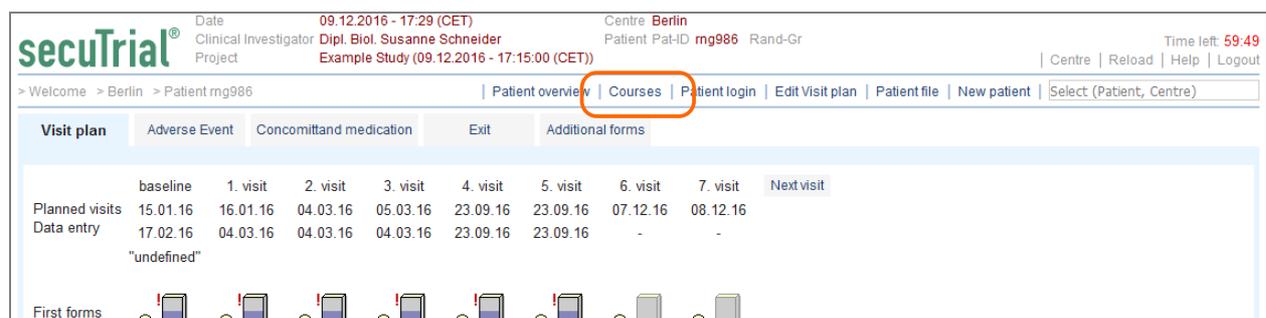


Fig. 2: New menu option (highlighted) in the form overview of the patient



Fig. 3: New menu option (highlighted) in the open form of the patient.

On the left-hand side of the report window, all reports are listed which the current participant has the right to display. For "+ single" type reports, multiple links are listed which either display a full overview (symbol: solid circle) or the individual charts for the respective visits or events (symbol: circle outline).

The charts are displayed on the right-hand side of the report window. The first time the chart is generated and if there is a lot of data to process, a progress bar will be initially displayed.

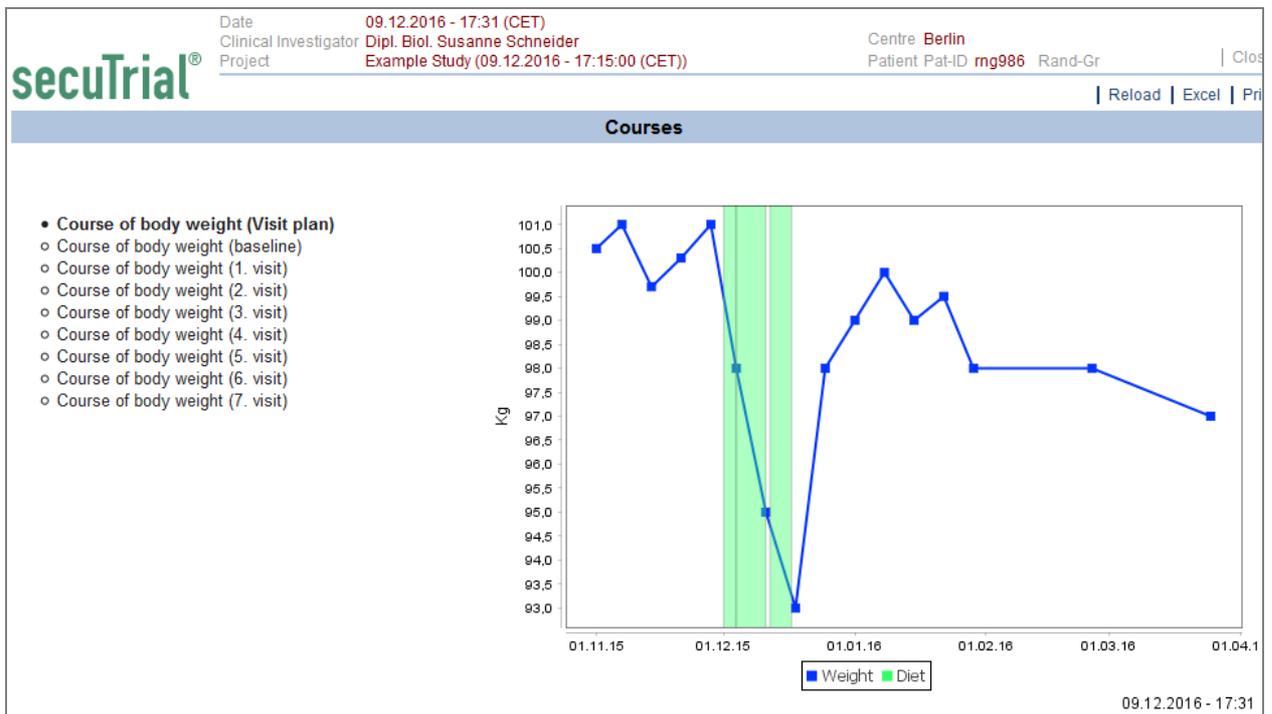


Fig. 4: Report window for value development charts - the list of possible links on the left, the generated chart on the right.

In the value development chart, the two axes depict the maximum value range on both the X axis and the Y axis. The presentation is labelled according to the displayed range. The first Y axis is displayed on the left, the second on the right. Any additional axes are alternately added on the left and right.

To include any values that have been modified in the meantime, click on the "Reload" button to generate the images again.

The data for the displayed chart can also be downloaded as an Excel file. With chronological presentation, the items with the same measurement date/time source (and end date/time source) are displayed in a table. The values are listed in the order of the forms in the patient. This order may deviate from the chronological order of the measurement date/time points.

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	Project		Example Study										
2	Date		09.12.2016 - 17:33 (CET)										
3	Clinical Investigator		Dipl. Biol. Susanne Schneider										
4	Patient		rng986										
5	Report		Course of body weight (Visit plan)										
6													
7	<b>Course of body weight rng986</b>												
8													
9		<b>Weight</b>	<b>(from)</b>	<b>(to)</b>	<b>Diet</b>								
10		2015-11-01	100,5										
11		2015-11-07	101										
12		2015-11-14	99,7										
13		2015-11-21	100,3										
14		2015-11-28	101										
15		2015-12-04	98	2015-12-01	2015-12-04	true							
16		2015-12-11	95	2015-12-04	2015-12-11	true							
17		2015-12-18	93	2015-12-12	2015-12-17	true							
18		2015-12-25	98										
19		2016-01-01	99										
20		2016-01-08	100										
21		2016-01-15	99										
22		2016-01-22	99,5										
23		2016-01-29	98										
24		2016-02-26	98										
25		2016-03-25	97										
26													
27													

Fig. 5: Excel export of the value development chart in Fig. 4.

When printing out the report window, only the currently displayed image of the selected value development chart is printed. The list of reports is not included in the print-out.

### Chart examples

Here are a few examples of different chart types for depicting the development of values.

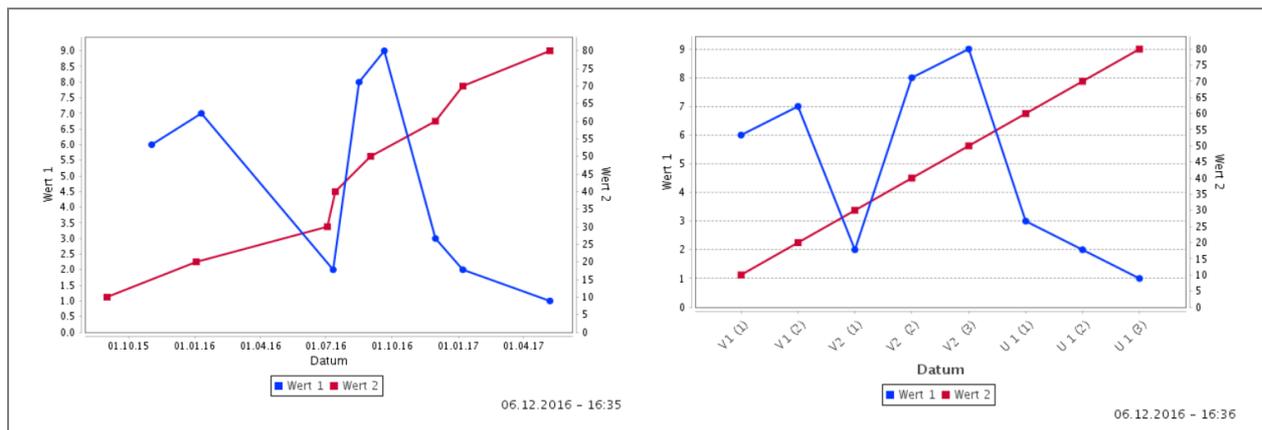


Fig. 6: Chart displaying two values with different value ranges as a line chart, left chronological, right sequential.

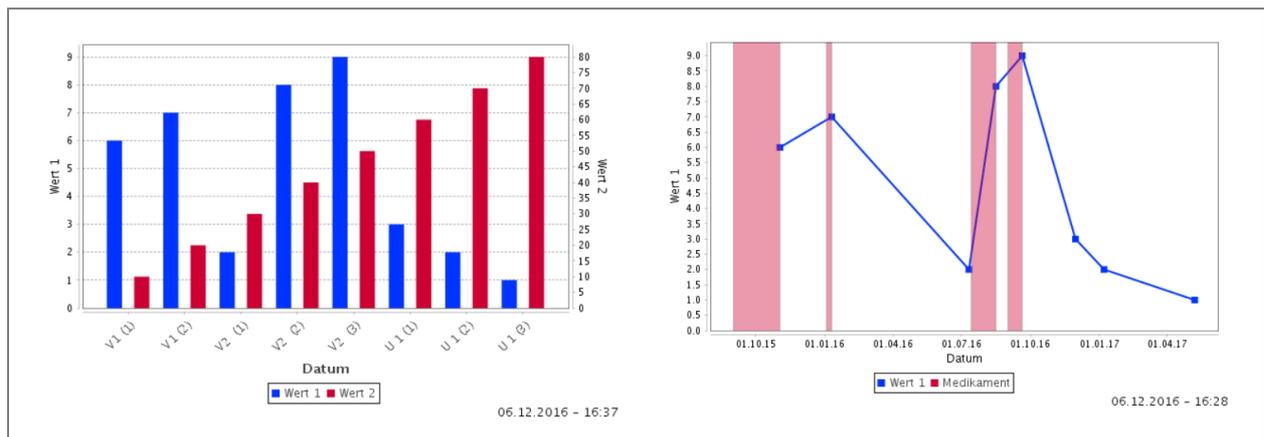


Fig. 7: Left: Sequential representation of two values, this time shown as a bar chart. Right: a measurement value with a marker value (range) in a chronological line chart.

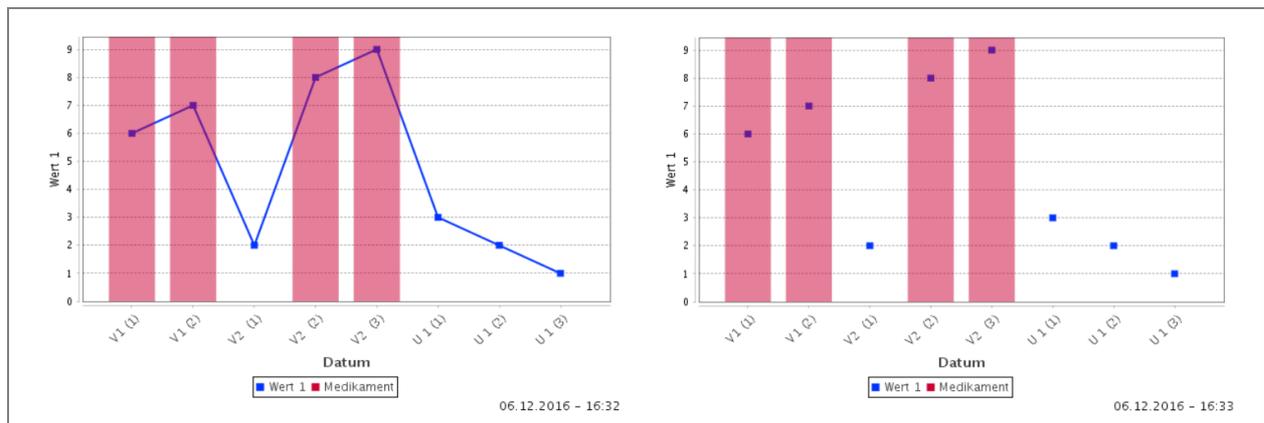


Fig. 8: Sequential presentation of a measurement value with a marker value as a line chart (left) and scatter chart (right).

## 2. New rule "Display value from ..."

ST5.1-2, #6122

A new "Display value from ..." rule has been introduced for displaying non-editable, non-saveable values from other forms. In this rule, the value which is to be displayed can be defined as a rule condition. The value is integrated into the interface via a placeholder.

### Rule definition (FB)

This new rule can only be created for "Layout dummy" type items. This restriction was introduced because this item type is not used in other form functions or displays, e.g. for query editing or in the Audit Trail. It is not possible to evaluate rules for these uses of the item texts.

The value which is to be displayed is defined as a rule condition, similar to a "Take value from" rule. Only one condition can be defined for the displayed value. However, it is possible to additionally specify one or more pre-conditions for displaying the value. The value will then only be displayed if the pre-conditions are fulfilled.

Multiple value display rules can be defined for one item. The rules can use the same placeholder or a different placeholder. If multiple rules are using the same placeholder, the value of the last fulfilled rule (in the defined order) will be displayed. The placeholder created when setting up the rule condition is only a suggestion. You should make sure that the value can be clearly distinguished from the normal item text.

The rule cannot be defined for layout dummies in repetition groups.

Item: This are the displayed values: { Layout-Dummy } <>  
 Rule: Date from centre form { Display value from ... }

Sequence position: 10 Or 10 And

Compare or Assign Operator: \* assign value Placeholder: \$10\$ ?

Compare Value: \* Item

Compare value from following item: \* Form: Centre form 1 <mpias0centre1>  
 Item: Some basic data - Date of inclusion into study <datum>

Compare value from following source: \* Centre

Fig. 9: Definition of a "Display value from ..." rule condition with specification of placeholder (highlighted).

On the editing page of the item, the defined placeholders are listed in the rule overview at the bottom of the page under "Contained rules" in the column "Following action". This can be helpful for formulating the item text using the placeholder.

Type: \* Layout-Dummy

Displayed order: 5 Shown no.:

Item: These are the displayed values:  hide label in form ?

Item (HTML):

Width in pixel: 500

Label (HTML): Text with date '\$10\$' and sex '\$20\$' ?

Contained rules (2)					
Displayed order	Name	+ / -	Type	Following action	Delete from database
▶ 15	Date from centre form	+	Display value from ...	Replace placeholder \$10\$ ?	Delete
▶ 25	Value from visit form	+	Display value from ...	Replace placeholder \$20\$ ?	Delete

Copy rule from ... New rule

Fig. 10: Overview of multiple "Display value from ..." rules in a layout dummy item.

### Display in form (DC)

When displaying the layout dummies in the opened form, the placeholders contained in the item texts are replaced with the referenced values according to the definitions. If no value can be displayed, either because the preconditions have not been fulfilled or because no value has been entered for display (NULL), the placeholder will be removed from the display without replacement.

> Welcome > Patient rng986 > Basic information | Patient overview | Courses | Import

**Basic information** Help

Standard Group

These are the displayed values: Text with date '22.09.2016' and sex 'female'

Treatment arm   Arm A  Arm B

Existing allergies   not applicable  
 cats  
 dogs

Fig. 11: Excerpt from the above example form in which both placeholders have been replaced with entered values.

### Patient file (DC)

Unlike in the form, no values are displayed in the patient file. The placeholders are only removed.

The function of this new rule is to help the user when entering data by directly displaying any important comparison data. This data has already been entered in other forms. It is therefore not necessary to display these values again for the patient file, as it is only intended for documentation purposes.

3. Options for displaying the audit trail sT5.1-3.2, #7068

### Configuration in the project (FB)

The way in which the audit trail is displayed for forms can be configured for each project. The following options are available:

- complete Audit Trail  
Displays the changes per question, shows all editing processes (also without data change), lists all repetitions per editing process for repetition groups
- History (changed questions only)  
Shows changes per question, only displays editing processes in which at least one item was changed in the question. Lists all repetitions per editing process for repetition groups.
- History (changed items only)  
Shows the changes per item, only displays editing process in which the item value was changed. Displays the changed items per repetition for repetition groups.

The last option is new. If this representation display is selected, only the individual changed item values are listed together with the editing date and participant.

Since the introduction of the current version, this configuration only determines the initial display of the audit trail in the form. The participant can then independently switch between the different representation options in the audit trail window in DataCapture (see below).

An online help text is available to explain the configuration.

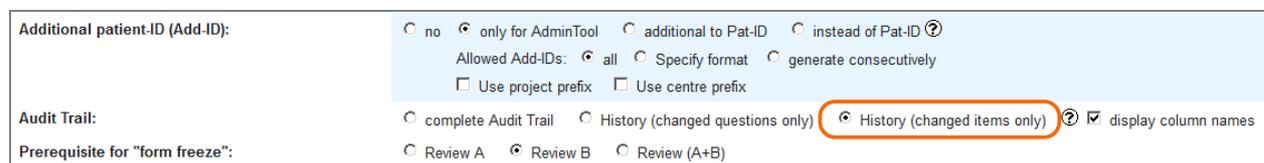


Fig. 12: Excerpt of the project configuration page with the new display option (highlighted) for determining how the audit trail is displayed.

### Display in form (DC)

The participant can choose between three different ways of displaying the audit trails with the newly introduced options. The option configured for the project determines the initial display.

**Note:** The layout for displaying the document changes in the audit trail has been revised. Changed items are now displayed as the most important entry on the left-hand side at the beginning of the row. The date and participant are displayed on the right.

Date	09.12.2016 - 18:16 (CET)	Patient	Pat-ID iut012 Add-ID 147
Clinical Investigator	Dipl. Biol. Susanne Schneider	1. visit	01.01.2016 (CET)
Project	Example study 2 (09.12.2016 - 18:16:45 (CET))	Form family	Examination
Centre	Stuttgart	Form	Scale 1

| Print | Close

Audit Trail "Scale 1" <span style="float: right;">Document-No. 3</span>			
Document History			
Participant	at	Reason	Project version
Dr. Ulrike Jonas	04.10.2016 - 18:53:25 (CEST)	Daten eingegeben	(04.10.2016 - 18:45:08 (MESZ))
Dr. Ulrike Jonas	04.10.2016 - 18:36:01 (CEST)	Daten eingegeben	(08.07.2016 - 19:44:03 (MESZ))
Dr. Ulrike Jonas	04.10.2016 - 18:34:10 (CEST)	Daten eingegeben	(08.07.2016 - 19:44:03 (MESZ))
Dipl. Biol. Susanne Schneider	09.05.2016 - 17:59:18 (CEST)	Daten eingegeben	(09.05.2016 - 17:51:38 (MESZ))
Dipl. Biol. Susanne Schneider	09.05.2016 - 17:50:56 (CEST)	Daten eingegeben	(09.05.2016 - 17:48:14 (MESZ))

Changes in document			
<input type="radio"/> complete Audit Trail <input type="radio"/> History (changed questions only) <input checked="" type="radio"/> History (changed items only)			
General measurements			
Value A	3	04.10.2016 - 18:34:10 (CEST)	Dr. Ulrike Jonas
		09.05.2016 - 17:59:18 (CEST)	Dipl. Biol. Susanne Schneider
	1	09.05.2016 - 17:50:56 (CEST)	Dipl. Biol. Susanne Schneider
Value B		09.05.2016 - 17:59:18 (CEST)	Dipl. Biol. Susanne Schneider
	1	09.05.2016 - 17:50:56 (CEST)	Dipl. Biol. Susanne Schneider
Date of measurement	21.10.2016	04.10.2016 - 18:53:25 (CEST)	Dr. Ulrike Jonas
		09.05.2016 - 17:50:56 (CEST)	Dipl. Biol. Susanne Schneider
Measurement done as required?	yes	04.10.2016 - 18:53:25 (CEST)	Dr. Ulrike Jonas
		09.05.2016 - 17:50:56 (CEST)	Dipl. Biol. Susanne Schneider
1			
Measurements in short sequences			
Part value a:	2	04.10.2016 - 18:34:10 (CEST)	Dr. Ulrike Jonas
	1	09.05.2016 - 17:50:56 (CEST)	Dipl. Biol. Susanne Schneider
2			
Measurements in short sequences			
Part value a:	3	04.10.2016 - 18:34:10 (CEST)	Dr. Ulrike Jonas
	2	09.05.2016 - 17:50:56 (CEST)	Dipl. Biol. Susanne Schneider
3			
Measurements in short sequences			
Part value a:	4	04.10.2016 - 18:34:10 (CEST)	Dr. Ulrike Jonas
	3	09.05.2016 - 17:50:56 (CEST)	Dipl. Biol. Susanne Schneider
4			
Measurements in short sequences			
Part value a:	6	04.10.2016 - 18:36:01 (CEST)	Dr. Ulrike Jonas
	5	04.10.2016 - 18:34:10 (CEST)	Dr. Ulrike Jonas

Fig. 13: Audit trail window with options for displaying changes (highlighted).

Displaying only changed items makes the list very compact.

For repetition groups, the data is compared per repetition. If a repetition is finally deleted, this is displayed as a value change to "NULL" (empty value). The deletion of a repetition at some intermediate point will cause all following values to be shifted to a lower position. As other values are then compared with each other, this will probably be displayed as a value change for all following positions (repetition numbers). A new repetition is only listed after the first change.

### Display in the patient file

When the patient file is downloaded including the audit trail, the audit trail is inserted below each form. The type of display option is now determined by the display type configured for the project.

#### 4. Delete confirmation for repetition group sT5.1-3.3, #7102

It was already possible to configure whether the "Delete" button should be displayed for a repetition group. If this button was clicked on in the form in DataCapture, the repetition was deleted without any further confirmation.

To prevent accidental deletion, for each repetition group it is now possible to configure whether the question "Do you really want to delete this repetition?" should be displayed after clicking on the "Delete" button. Only when this is confirmed with "OK" will the repetition actually be deleted.

### Configuration per question (FB)

Subform: *	<input type="text" value="testsub"/> <emnpias4testsub>	Initial count: *	<input type="text" value="1"/>
		Maximum count:	< Please choose >
		Show "Delete" button:	<input checked="" type="checkbox"/>
		Display delete confirmation:	<input checked="" type="checkbox"/>
		Reverse repetitions:	<input type="checkbox"/>
		Hide headline:	<input type="checkbox"/> ?

Fig. 14: Excerpt of question configuration for handling of subforms with new confirmation option (highlighted).

The confirmation prompt can be configured when setting up the repetition group. The option is only available if the "Delete" button is displayed.

### Form display (DC)

Fig. 15: Confirmation prompt upon clicking on the "Delete" button for an accordingly configured repetition group.

After clicking on the "Delete" button, the confirmation prompt is then displayed. The minimum number of repetitions configured in the repetition group remains the same after clicking on delete. Only the entered data is deleted, the repetition itself remains unaffected and is always displayed.

### Miscellaneous

#### 5. Revert project setup to productive version (FB) sT4.5-1.3, #4404, #8459

After a project has been set to productive mode, it is still possible to make changes to the project setup. These are applied with the next release of the productive version of the project.

It is now possible to undo all changes that have been made since the last productive version in a single step. A new "Revert" link has been introduced for this on the project overview page. The link is only available if the project has already been set to productive mode and the logged in participant either has the participant right to create new projects or the "Release" role right for the displayed project.

Project name: *	Example study 2		
Version:	Development	Release:	By:
	Vers. label: <input type="text"/>	Vers. no.: 2	Last vers. modification: 09.12.2016 - 18:19:16 (CET)
Project setup	<a href="#">Export/import project setup</a>	<a href="#">Compare project setup</a>	
Release:	<a href="#">Release</a>	<a href="#">Revert</a>	

Fig. 16: Excerpt from the project overview page with the link to revert the project (highlighted).

On the revert page, only an active link for opening the project version comparison is initially displayed. To perform the revert procedure, the comparison window must first be opened.

**secuTrial®** Date: 09.12.2016 - 18:23 (CET) Participant: Dipl. Biol. Susanne Schneider Time left: 59:48 | Logout

[Welcome](#) > [Project](#)

**Revert project 'Example study 2 (IAS4)' to productive version**

**Productive version**

No. 1 from 09.05.2016 - 17:51:38 (CEST) "1.0" "wawr" Schneider, Susanne, Dipl. Biol. <susanne>

The project will be reverted to the current productive version.  
All changes made since the last transfer to production mode will be lost.

Please review all changes to the project before reverting it.

[Compare project setup](#)

Fig. 17: Initial page for reverting a project: only the link for the version comparison is active.

**Note:** Before reverting to the previous productive version, you should always perform a version comparison between the productive version and the development version of the project so you know which changes will be deleted!

Only after performing the comparison can the development project be reverted back to the productive project. After clicking on the active button, an overlay will be displayed with a confirmation prompt. Only after confirming will the project then be reverted.

**Important:** It is not possible to undo the revert procedure!

**secuTrial®** Date: 09.12.2016 - 18:23 (CET) Participant: Dipl. Biol. Susanne Schneider Time left: 59:14 | Logout

[Welcome](#) > [Project](#)

**Revert project 'Example study 2 (IAS4)' to productive version**

**Productive version**

No. 1 from 09.05.2016 - 17:51:38 (CEST) "1.0" "wawr" Schneider, Susanne, Dipl. Biol. <susanne>

Do you really want to revert to the current production mode release?  
All changes made since the last release will be lost.

**This transaction cannot be undone!**

Fig. 18: Confirmation prompt for reverting the project setup

A progress window will be displayed while the project is being reverted.

**6. Calculation of the sum status icon (DC) sT5.1-3.2, #6681**

When calculating the sum status for form family icons in the form overview of the patient and the display in the icon report, all forms that are frozen as the result of rules are now no longer taken into account.

It is now possible for the sum status icon to be complete although the frozen forms have not been or have only partly been completed or reviewed. Queries or comments that have been created for forms which have been frozen as a result of rules are no longer displayed in the sum status.

This correction applies for the following statuses:

- Completion status
- Data entry complete (DEC)
- Errors and warnings
- Query
- Comments
- Review
- Source Data Verification (SDV)

**7. "Event" column in the discrepancies report (DC) #8625**

In the discrepancies report, a new "Event" column has been introduced. The visit label for each visit is displayed in this column for all visit forms. Adverse events are displayed with the name of the event and the date of the follow-up examination. Casenode forms are displayed with the name of the form family.

Discrepancies (14 / 14)												
Dcr-No. (Q)	Test-No	Test-Date	Patient	Centre	Document-No	Form	Item	Event	Last edited	Participant	Status	
<input type="checkbox"/>	All	< All >	< All >	< All >	< All >	< All >	< All >	< All >	< All >	< All >	new	
1	<input type="checkbox"/>	1	1	06.10.16	Isy963	Berlin	30	Conco. medication - Type of administration	Concomittand medication	06.10.16	Dipl. Biol. Susanne Schneider	new
2	<input type="checkbox"/>	2	1	06.10.16	Isy963	Berlin	30	Conco. medication - Type of administration	Concomittand medication	06.10.16	Dipl. Biol. Susanne Schneider	new
3	<input type="checkbox"/>	3	1	06.10.16	vts233	Berlin	166	Conco. medication - Type of administration	Concomittand medication	06.10.16	Dipl. Biol. Susanne Schneider	new
4	<input type="checkbox"/>	4	1	06.10.16	vts233	Berlin	166	Conco. medication - Type of administration	Concomittand medication	06.10.16	Dipl. Biol. Susanne Schneider	new
5	<input type="checkbox"/>	5	1	06.10.16	rng986	Berlin	236	Basic information - Existing allergies	5. visit	06.10.16	Dipl. Biol. Susanne Schneider	new
6	<input type="checkbox"/>	6	1	06.10.16	rng986	Berlin	233	Basic information - Examination done?	3. visit	06.10.16	Dipl. Biol. Susanne Schneider	new
7	<input type="checkbox"/>	7	1	06.10.16	rng986	Berlin	230	Basic information - Date of diagnosis	2. visit	06.10.16	Dipl. Biol. Susanne Schneider	new
8	<input type="checkbox"/>	8	1	06.10.16	rng986	Berlin	229	Basic information - Comments	1. visit	06.10.16	Dipl. Biol. Susanne Schneider	new
9	<input type="checkbox"/>	9	1	06.10.16	mjm778	Berlin	192	Basic information - Value 1	baseline	06.10.16	Dipl. Biol. Susanne Schneider	new
10	<input type="checkbox"/>	10	1	06.10.16	mjm778	Berlin	192	Basic information - Value 2	baseline	06.10.16	Dipl. Biol. Susanne Schneider	new
11	<input type="checkbox"/>	11	1	06.10.16	Isy963	Berlin	28	Adverse Event - Start of event	1. Adverse Event - 01.01.16 - 12:00	06.10.16	Dipl. Biol. Susanne Schneider	new
12	<input type="checkbox"/>	12	1	06.10.16	Isy963	Berlin	28	Adverse Event - End of event	1. Adverse Event - 01.01.16 - 12:00	06.10.16	Dipl. Biol. Susanne Schneider	new
13	<input type="checkbox"/>	13	1	06.10.16	Isy963	Berlin	30	Conco. medication - Type of administration	Concomittand medication	06.10.16	Dipl. Biol. Susanne Schneider	new
14	<input type="checkbox"/>	14	1	06.10.16	vts233	Berlin	166	Conco. medication - Type of administration	Concomittand medication	06.10.16	Dipl. Biol. Susanne Schneider	new

Fig. 19: Excerpt from the discrepancies report with the new "Event" column.

This column is displayed to provide additional information. Due to the varying content, it is not possible to sort or filter by this column.

**8. Displaying rule references in all project versions (FB) #8361, #9089**

Even if the project has not yet been set to productive mode, form setup elements cannot be deleted if there any external references to these elements which would be rendered incomplete if they were deleted. For such elements an information text is displayed instead of a "Delete" button. Clicking on this information text opens a pop-up window in which all the external references are listed.

This information text and the pop-up are now also displayed if the project has already been set to productive mode and for this reason the element can no longer be deleted. This information text is displayed in all project versions (also in the productive and archive versions). Via the pop-up containing the list of external references, you can jump directly to the respective editing pages. It is then obviously only possible to edit the references in the development version.

In all projects you can now activate the display of rule references by clicking on the new checkbox located above the links. In contrast, the deletion check is always performed – even without the activated reference check.

Form families (13)				<input checked="" type="checkbox"/> Check references
Displayed order	+ / - Form family name	Type	Hidden	Delete from database
▶	+ Subform	Subform		<a href="#">Display references</a>
▶ 1	+ First forms	Visit		<a href="#">Display references</a>
▶ 11	+ MIV	Visit		
▶ 21	+ DDE	Visit		

Fig. 20: Excerpt from the form family overview of a productive project with the checkbox activated for checking rule references (highlighted).

**9. Pre-selection of project when creating new centres (AT) #8424**

When creating a new centre, the project must be selected as a key property. After saving, this assignment can no longer be modified.

To ensure that users intentionally select a project, the project is only pre-selected if the centre overview has already been filtered by this project.

**10. Sorting of roles for resource editing (AT) #8558**

On the resources overview page and the page for editing resource rights, the roles are now listed by internal role names in alphabetical order.

**Fixed issues**

**All tools**

#8170 The message text on the general error page was not very well phrased.

The wording has been optimised.

#8245 The configuration parameter "statistic\_generation\_time" was entered in the CustomerAdminTool configuration file, the parameter "dailyrestarttime" was entered in the FormBuilder configuration file. The parameter "statistic\_generation\_time" is also used in the ExportSearchTool to start the automatic export, the parameter "dailyrestarttime" is used in the CustomerAdminTool to activate newly created customers. Changes to the entered times therefore did not take effect in the other tools.

These configuration parameters have been moved to the general configuration file (see also: Deployment).

#8891 In the documentation for the database table `attpxcvpchangelog` there was a spelling mistake in the German version.

The spelling has been corrected.

**CustomerAdminTool**

#3847 The library used to generate the images for statistics was out of date.

The library has been updated.

**Note:** The order of the colours used for the graphics has also been changed as follows: Blue, green, yellow, orange, purple, red (previously: red, blue, green, yellow, orange, purple).

#9073 When generating statistics of the type "Patient by centres", an error (exception) occurred if there were no centres or patients. These statistics could not be displayed.

This issue has been fixed.

#9135 When editing the password file via the PwdManager, it was not possible to add a new user with an email address. The process was always rejected with the error message "Invalid email", even if the address was valid. However, it was possible to subsequently add an email address to an existing user.

This issue has been fixed.

## FormBuilder

#8575 In the dossier the documentation was missing for the project-specific texts for "New adverse event" and "New follow-up examination".

The documentation has been added.

#8913 If when editing the layout of an item matrix the displayed matrix is reduced by an already added item, a small pop-up window is displayed asking whether this action (which deletes items from the matrix display) should really be performed. If this question was dismissed by clicking on "Cancel" and the user then clicked on the "Adopt" button, an error message was displayed and the edited matrix could not be saved.

This issue has been fixed.

#8974 In certain cases, saving a visit plan was rejected with the error message "All immediately created visits must be either fixed type or flexible", even though the visit plan preview did not indicate any incorrect configuration. This problem occurred if some of the scheduled visits had already been repeated (e.g. in a group) from the immediately created visits and the subsequent visit templates had been defined as unscheduled visits.

This issue has been fixed.

#9052 In projects with configured DDE function, the DDE function could also be configured for forms without a database table. However, the DDE function was not performed for these forms in DataCapture.

This issue has been fixed. A DDE configuration is no longer offered for these forms.

#9068 In projects with centre forms, reports can also be defined from these forms via individual fields. If all items defined as fields in this report are defined as hidden after the project is set to productive mode, it is not possible to display them in the report. Such definition errors were not displayed in FormBuilder or checked in DataCapture (reports with definition errors should not be listed).

This issue has been fixed.

#9070 The print view of individual field centre reports did not display the contained items. The same error occurred in the project dossier.

This issue has been fixed.

#9071 For items with saved numeric values in individual field reports, limit values can be defined from which the item value is to be displayed in a different CSS style. This definition is possible for number items as well as for radiobutton items and pop-up items. In the print view, this limit value definition was only documented for number items and not for radiobutton or pop-up items. The same error occurred in the project dossier.

This issue has been fixed.

#9087 The names of projects must be unique. This is checked when a user creates a new project, imports an entire project setup or edits the project configuration. If the name of a project is changed after setting the project to productive mode and the project is then set to productive mode again, it is possible to create a new project with the old project name. However, in the archived project it was no longer possible to access the form families via the project overview page. The error message "There is already a project with this name, please enter a different name." was always displayed.

This issue has been fixed.

#9088 Within a subform family in a project, it is possible to create any number of forms as test forms. One of these forms can then be selected for the actually used project test. However, if the first created test subform was not selected for the test, it was recognised as selected during the deletion check (it was no longer possible to delete the family) but the form was not displayed in the reference window of the subform family.

This issue has been fixed.

#9126 There was a spelling mistake in the English label for configuring the project-specific text.

The English spelling has been corrected.

#9134 When listing and editing project messages, messages for creating a new patient were sometimes incorrectly marked with a clock symbol even though they were not time-controlled messages and were sent directly. This error occurred if the message had been previously created with a time-controlled trigger.

This issue has been fixed.

#9149 When defining a rule condition with a metadata comparison for a fixed text, an error (exception) occurred upon selecting the type of comparison value ("Fixed text") if the source item was not a text item. It was then no longer possible to edit the condition.

This issue has been fixed.

## DataCapture

#8299 On the login page, the default text reminded users to comply with SOPs even though such working procedures are not necessarily required for all projects. This message also appeared on the change password page which can be accessed from the login page.

The references to SOPs have been removed from the default text.

#8675 When using the print function for the validation report, an error (exception) could occur if the report contained error messages which referred to items that had since been deleted.

This issue has been fixed. Error messages originating from deleted items are no longer displayed.

#8946 In the form view for forms without a database table (print or display forms), the menus for editing queries and comments were displayed if this function was directly configured for the form or via the project, even though this function cannot be performed for non-saveable forms.

This issue has been fixed. The configuration in FormBuilder has been removed for these forms.

#9018 When accessing a patient via the search window, an error (exception) could occur if the patient was not assigned to a project.

This issue has been fixed.

## Issues fixed during development

The following issues were found during development and fixed:

#8213, #8258, #8273, #8293, #8382, #8383, #8387, #8389, #8399, #8463, #8464, #8522, #8523, #8524, #8531, #8532, #8537, #8533, #8575, #8579, #8580, #8593, #8594, #8606, #8609, #8611, #8613, #8614, #8615, #8617, #8627, #8628, #8630, #8638, #8649, #8650, #8655, #8656, #8660, #8661, #8663, #8664, #8668, #8786, #8880, #8967, #8978, #8979, #8983, #8987, #8988, #8995, #8998, #8999, #9000, #9001, #9002, #9003, #9004, #9006, #9007, #9008, #9009, #9010, #9011, #9015, #9017, #9019, #9020, #9021, #9023, #9030, #9031, #9046, #9049, #9050, #9054, #9055, #9058, #9059, #9060, #9062, #9063, #9066, #9069, #9090, #9091, #9092, #9023, #9094, #9095, #9096, #9097, #9101, #9102, #9104, #9110, #9111, #9112, #9115, #9116, #9117, #9118, #9119, #9120, #9122, #9124, #9127, #9128, #9129, #9132, #9136, #9140, #9143, #9145, #9148, #9155

## Deployment

### Database

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

### Configuration

**#8245**

The following configuration entries need to be copied from the files

```
setup.FormBuilder.cfg
setup.CustomerAdminTool.cfg
```

to the file

```
*.secuSuite.cfg
```

```
#####  
# application-function configuration  
#####  
# time of day at which the automatic restart for project release can occur  
# format hh:mm  
#dailyrestarttime = 03:30  
  
# time for statistic generation and the start of the automatic export.  
# make sure that there is enough time between this time and the time above and  
# any normal WOMonitor schedule to generate all statistics (if there are very  
# many statistics it may be necessary to adjust these times).  
# format hh:mm  
#statistic_generation_time = 02:30
```

**Important:** The check for a valid configuration has been changed. If any invalid option (that includes unused but set obsolete options) is configured, the tools will not start-up! In such a case please check the output in the log file and remove all options from the respective configuration files that has been listed as "obsolete\_option".



# secuTrial® 5.1.0.21 – Release notes



## New functions

### Output of form name in export webservice

**#8883**

The output of the ProjectDataWebservice has been extended. Additionally to the form tablename the displayed form name from the patient's form overview is now given as a new property "name" in the FormStatusBean.

The list of forms now includes also forms that are used as print-only or display-only forms and that are not stored in the database. For these forms the form tablename will be unset and they do not provide a usable form status.

The definition of the **FormStatusBean** is therefore now:

form	Database table name of the form (unique within the project)
name	Displayed form name from the form overview
status	Form status (as <b>DocumentStatusBean</b> )

## Fixed issues

### All tools

#9125 The JDBC driver used by secuTrial® was outdated. It required the configuration of an old logon version in the Oracle network configuration.

The JDBC driver was update to the version 11.2.0.4 (see deployment: Database #9125).

### CustomerAdminTool

#9156 On the customer editing page in the section "Extended functions" the short names for the different functions were displayed twice.

The display has been corrected.

### FormBuilder

#9157 During validation before saving of a course-of-values report some of the error messages were displayed in English even if the user interface had been set to German.

The issue has been fixed.

#9233 The English terms for the defintion of course-of-values reports were neither well phrased nor well chosen.

The terms were corrected as follows:

<i>old</i>	<i>new</i>
Course of values	Value development
Course on	Development of
Disposition	Presentation (Deutsch: Darstellung)

### DataCapture

#9208 Values of date items were displayed in reports of the type "single field per visit" in the format "DD.MM.YYYY". When exported from the report into Excel the values were formatted differently as "YYYYMMDD".

The issue has been fixed. Date and time items are now formatted in Excel similar to the online display.

#9222 The discrepancies report can be sorted and filtered by the displayed columns. In the title bar the numbers of currently displayed and overall discrepancies are shown. If the report was sorted after filtering the overall list had been erroneously set to the filtered list. That error was only resettable by re-open the report.

The issue has been fixed.

#9238 If a message has been specified for answering queries, that message was not triggered if a query was automatically answered due to a value change.

The issue has been fixed.

#9253 When displaying a value-development report it could happen that the existing item values were not displayed in the chart with the correct colour coding.

The issue has been fixed.

## Fixed Issues from 5.0.3

### FormBuilder

#9246 In projects with very many items (some thousands) the opening of the implementation view of a single form could last so long that the result could not be displayed (error message: "no instance available").

The performance of the implementation view has been optimized. For very elaborated projects the display of the overall implementation view may still be an issue.

### AdminTool

#9144 It can be set per participant that he / she is automatically assigned to new created centres with a specific role. If a customer area contained multiple projects and participants had different configurations related to future-centre-assignments in these projects it could happen that the assignments were not made correctly during the creation of a new centre. The assignments of participants had then to be corrected manually.

The issue has been fixed.

### DataCapture

#8379 During calculation of scores the rounding of values exactly in between the next upper values (example: rounding of 1.5 to the next integer) had not been performed correctly. Instead of always rounding to the next upper value, the next even number has been used (example: before=1.5, rounded=2, before=2.5, rounded=2).

The issue has been fixed. When the calculation is exactly between two values the next upper value is now always used.

**Note:** This fix is only applied when performing a new score calculation (clicking on the score-button, saving the form with rule-evaluation, revalidation).

#9224 In the discrepancies report queries could always be created even if the related document was currently edited by another participant. The issue existed for the single as well as for the multiple query creation.

The issue has been fixed.

#9232 There were error lines in the log file ("IASEOutilities.subdocumentForFormgroupAndPosition") when a form with a repetition group was edited although there had been no error condition.

The log file output has been removed.

#9250 The hide-rule was not evaluated correctly in the non-editable display mode (e.g. after form save) of a patient form, if one of the rule conditions referred to an item value in a centre form.

The issue has been fixed.

## Fixed issues from 5.0.2

### DataCapture

#9230 Rule conditions with references to lookup or number items were not always evaluated correctly. For lookup items an empty string was used in the condition instead of the value text of the actual selected item. For number items a similar error only occurred during import. The results of the erroneous condition evaluation depended on the respective rule types.

The issue was fixed. Depending on the error implication a new form save with complete rule evaluation may be necessary for complete correction.

## Fixed issues from 5.0.1

### DataCapture

#9240 During score calculation the parameters for multiplication or division were always replaced by "1" (as a neutral operation) if the referenced item value was unset. This could result in a performed calculation although no item value was given.

The issue has been fixed. Without a referenced item value the corresponding calculation step will not be performed.

**Note:** This fix is only applied when performing a new score calculation (clicking on the score-button, saving the form with rule-evaluation, revalidation).

## Fixed issues from 4.9.1

### AdminTool

#9197 From the project editing page the centres of the project can be selected for editing. If a selected centre was deleted an error (exception) occurred during the page change back to the project editing page. The deletion was nevertheless performed correctly.

The issue has been fixed.

### DataCapture

#9225 Before a query shall be created on a selected discrepancy in the discrepancy report an editing lock is created on the respective document. This editing lock was not deleted if the report was re-initialized via the "reload" button before the query was stored. The documents could not be edited again until the session had been terminated.

The issue has been fixed.

## Deployment

### Database

**#9125**

The JDBC driver used by secuTrial® was updated to the version 11.2.0.4 (this is the latest version still supporting Oracle 9).

The logon version in the network configuration of Oracle can therefore also be set to "11" for the use with secuTrial®.



# secuTrial® 5.1.0.22 – Release notes



## New functions

### Configuration of the number of characters for the pseudonym search field #9256

The minimal number of characters to start the search for pseudonyms (and centres with centre-forms) can now be configured per customer in the CustomerAdminTool.

In order to do this the minimal number to start the autosuggestion can be selected on a list from 2 to 20 characters on the customer editing page in the section "Administration tools".

The screenshot shows the 'Administration tools' configuration page. It includes several sections: 'All tools' with input fields for password length (8), password expiration (6), and wrong password count, and a checkbox for 'timeout notice'; 'AdminTool' with checkboxes for 'Deletion of centres', 'Edit Add-ID of patients', and 'Importing patient lists' (checked), and a 'Default filter date (months)' field; 'ExportSearchTool' with a dropdown menu set to 'CSV format for MS Excel'; and 'DataCapture' with a 'Sessiontimeout (minutes)' field and a note 'Sessiontimeout Server = 60 Minutes'. The 'Characters autosuggest' field is highlighted with a red circle and contains the value '2'.

Fig. 1: Configuration of the numbers of characters for the pseudonym search on the customer editing page (markup).

### Configuration of the button label for value-development reports #9283

The terms for the configuration of the value-development reports in the FormBuilder have been optimized in the previous secuTrial® version, especially for the English display (see #9233). The button label for the report window in the DataCapture can now be configured per project.

The list of project specific labels on the visit plan editing page has therefore been extended with a new section for this button label. The default label text has furthermore changed from former "courses" to now "Value developments" for similar wording.

## Fixed issues

### FormBuilder

#9262 The warning before resetting a project to the productive version was not well phrased in English.

The English message has been optimized.

#9280 In a project without visit forms and without visits the data record table could not be created (exception).

The issue has been resolved. If there is neither a visit nor visit forms in a project the section for the visit plan is omitted in the form-overview tab of the data record table.

#9284 When defining rules in centre-subforms other items of the same centre-subform can be referenced in the rule conditions. As the source for that item references neither "same subform" nor "previous repetition" was provided, only "centre form".

The issue has been fixed.

#9287 During editing of a report of the type "free SQL" an information popup can be opened via the "i" icon with descriptions of all database tables for the current project. If a customized design had been used with dyed navigation buttons the popup contained only the text "send data" instead of the triangle buttons to toggle the single table descriptions.

The issue has been fixed.

## DataCapture

#9257 In the icon report separate columns were displayed for all casenode form families even if for a family all forms had been hidden per configuration (such family will not be displayed in the patient's form overview). The icons for that family were always displayed in white as non-storable forms.

The issue has been fixed. Hidden casenode form families are no longer included in the icon report.

### Fixed issues from 5.0.3

## DataCapture

#9254 When displaying the search results for centres and patients pseudonyms after entering characters into the search field results with short text length were displayed below results with longer text length ("ab" after "abc").

The sorting of the result list was reversed.

### Fixed issues from 5.0.1

## DataCapture

#9274 The randomization of a patient could not be performed if a score with the calculation of a numerical date / time interval (e.g. age in years) had been included into the randomization stratification algorithm. The error message "The Usage of stratification factor from type Days D-M-Y (nur berechnet) is not implemented." was displayed instead.

The issue has been fixed.

## Deployment

### Database

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