secuTrial® 5.0.1.10

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Introduction

This version features extended options for handling blinded studies and adverse events. General user friendliness has also been further improved.

The following new functions have been added:

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

New Functions

Unblinding   sT5.0-1

Configuration in the customer (CAT)

For the configuration of unblinding options for randomized studies, a new "Unblinding" customer configuration has been introduced to the additional features. This configuration applies for the following functions:

– Unblinded display according to role right
– Emergency unblind (can still be activated per project)
– Unblind with export

For existing customers, the new configuration is already automatically activated, as the old function "Unblind with export" may have already been used.
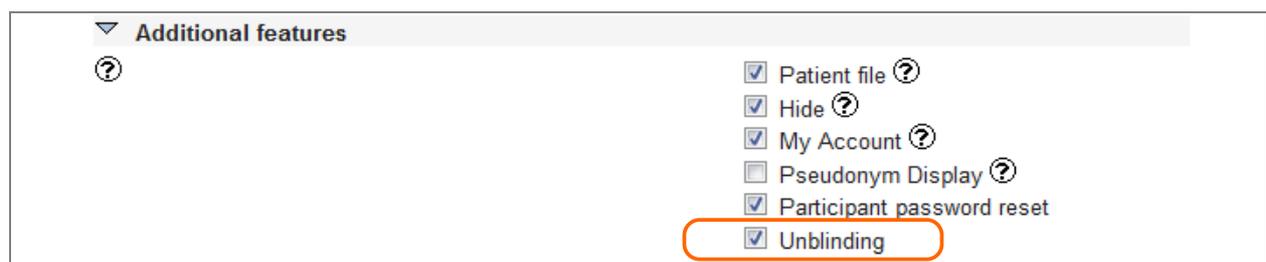
Fig. 1:   "Unblind" configuration for the "Additional functions" on the customer editing page.

If this configuration option is deactivated, the option in FormBuilder to configure emergency unblinding for a project will no longer be available. In the AdminTool, all role rights related to an unblinding function will no longer be displayed. Already unblinded exports will continue to be documented as before. All patients that have already been unblinded due to an emergency will also remain unblinded. In the participant and patient activity log, all patients displayed as unblinded via role right will likewise continue to be documented.

Configuration in the project (FB)   sT5.0-1.2, #5913

If unblinding has been activated in the customer (see above), the emergency unblind function can be additionally configured for randomized in the FormBuilder. This option can only be selected, if "Blinded" has also been selected.

Fig. 2:   "Emergency unblinding" configuration for randomization on the project configuration page.

The "Emergency unblinding" function can also be deselected again after the project has been set to productive mode. However, patients that have already been unblinded via this function will remain unblinded.

Displaying role rights and emergency unblinding (AT)   #8143

In the AdminTool, if unblinding has been activated in the customer (see above), there are two new role rights:

– Display unblinded
– Emergency unblinding

The role rights can be assigned independent of any unblinding function that is used in a project. These rights are also accordingly documented in the rights overview.

These role rights can only be assigned to participant roles.

Fig. 3:   New "Unblind" rights in the DataCapture rights on the role editing page.

When assigning the right for "Display unblinded" and "Emergency unblinding", a confirmation message will appear informing the user about the effects of assigning this right. Short online help texts are available to explain the functions.

1. Unblinded display by role right (DC, AT)   sT5.0-1.1, #6223

If a project has been configured with blinded randomization, the patient has already been randomized at least once and the participant's current role has the "Display unblinded" role right, when the participant accesses the patient the randomization group will also be displayed in the status header of DataCapture in addition to the randomization number.

When viewing the corresponding randomization form, both the number and the group of the randomization is displayed in the randomization item. This display is also used for printing out the patient file.

In the reports, only the patient's randomization number will continue to be displayed if this has been configured for the respective report.

The unblinded display of a patient is recorded in the activity log of both the participant and the patient. Only the first access per project is logged. If the same patient is viewed multiple times, this information is not repeatedly logged. If the same patient is unblinded and accessed by a different participant, this is also logged. The activity log for the participant and patient can be viewed by an administrator with the

corresponding right in the AdminTool. The entry will remain in the activity log even if the right or the entire unblinding function is deactivated.

2. Emergency unblinding (DC)	sT5.0-1.2, #5913

In the form overview of the patient, there is a new "Emergency unblind" menu option. It is available if at least one blinded randomization is used in the project, the patient has already been randomized and at least one of the following conditions is fulfilled:

– The emergency unblind function has been activated for the project and the participant's current role has the emergency unblinding right.

– The patient has already been permanently unblinded.

If the patient has already been unblinded, the unblinding history can be viewed via this menu option.

If the participant has the emergency unblinding right and if the patient has not yet been (fully) randomized, the patient can be unblinded via this option. In the case of the multiple randomization items, the item must first be selected and a reason for unblinding must be entered.

The user will then be prompted to confirm this action, after which the patient will be permanently unblinded. From then on, the randomization number and group will be displayed in the DataCapture status header and in the form.

Export randomization number and group (EST)

When performing an export – which requires the corresponding unblind export right – you can select whether the patients should be unblinded in the export. Previously, instead of the randomization number, the randomization group was exported in the same column in the "casenode" export table.

Now, two columns are exported in the casenode table, with one column containing the randomization number and the other the randomization group. If the patient has been permanently unblinded via the emergency unblind function, this unblinding is always performed without being explicitly selected and without any additional unblinding rights of the participant.

In the case of multiple randomizations in a project, two columns are exported in the casenode table for each randomization item.

A precise description of the export tables can be found in the "ExportFormats" documentation.

Extended adverse event functions

3. Editing the link labels "New Adverse Event" and "New follow-up" (FB)
sT5.0-3.2, #4988

The names of the two links "New Adverse Event" and "New follow-up", which are displayed in DataCapture under the adverse event tab of the form overview, can now be configured in the FormBuilder on a project by project basis. A different text can be entered for each language.

Fig. 4:   Editing options for the link labels in the section "Project-specific labels" on the visit plan page of the project.

4. Creating AE / SAE via rules	sT5.0-3.3, #5104

New rules for creating AE / SAE (FB)

Two new rules have been introduced for creating a new adverse event (=AE) or serious adverse event (SAE) from a visit or casenode form:

– "Create new adverse event if …"
– "Create new serious adverse event if …"

These rules are only available if an adverse event form family has been created for the project. The rules for creating a SAE can only be used if at least one SAE form has been defined in the project and if the AE / SAE workflow for the project has not been specified as rule based.

Unlike the rule "Open serious adverse event if ...", the two new "create" rules actually create a new adverse event rather than just converting the existing event.

In order to create the new event, depending on the project configuration, it may be necessary to enter the date on a prompt page. For the new event to be actually displayed, the first adverse event form must also have been saved.

Create AE / SAE via rule (DC)

When entering data in DataCapture, if a "Create new adverse event if ..." rule is fulfilled in a visit or casenode form, after saving the first adverse event form of the project will be added to the list of possible next forms. If instead or in addition one or more "Create new serious adverse event if... " rules are fulfilled, only the first form labelled as "SAE" will be added to the list.

The form rights for the adverse event forms and any form requirements based on this will also be checked. Only if these conditions are also fulfilled will the first editable form actually be offered as the follow-up form.

If the participant selects the AE / SAE as the next form, the prompt page for entering the event and examination date will be displayed if the option "Hide event and examination dates" was not selected in the project. In the AE workflow with pre-filled default selection, the option to create either an AE or SAE is already pre-selected on this page according to the fulfilled rule and cannot be changed.

After this – or immediately if this information is not meant to be displayed – the AE / SAE form will open and can be filled out. The new AE / SAE will then be created upon saving this form.

The original order of the visit or casenode forms will then continue, as is usual for the rule "Show form if...". After filling out the AE / SAE form, if the participant returns to the form overview of the patient, the list of following forms will be deleted.

5. Subsequent editing of AE / SAE date	sT5.0-4.6, #8103

Role right for subsequent editing of AE / SAE date (AT)

It is now possible to subsequently edit the dates entered for the creation of an AE / SAE or a follow-up examination. A new general role right has been introduced for this purpose which can be assigned to participant roles.

This new right can be assigned in the form of three different options:

– display history

   The participant cannot edit the data. However, if the data has been edited by another participant for a patient, the participant can view these changes.

– dllow editing

   The participant can edit the data for all adverse events and also view all changes made by other participants. This right also includes viewing the history.

– Hide edit option

The participant is not permitted to edit the data or view any existing editing history. On the adverse event form overview, the participant will not be shown the (newly introduced) menu option for editing or viewing the editing history.

In all existing roles, this new right will be automatically set to "display history".
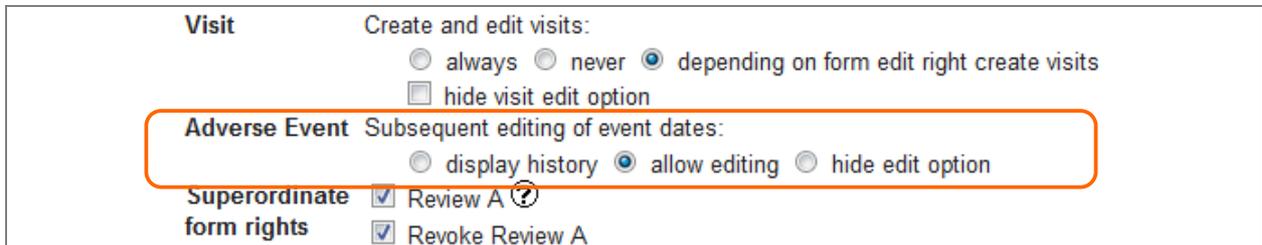
Fig. 5:   New section (highlighted) under general role rights for editing AE data.

Subsequent editing of patient AE / SAE dates (DC)

In the adverse event form overview in DataCapture, a new menu option can now be displayed for editing adverse event dates and viewing the editing history. This option is only displayed if the patient has already created at least one adverse event, the participant has the editing right or has already edited dates and the participant has the right to view the editing history.

Note: The menu option for editing the visit dates is now only shown in the form overview of the visit forms.
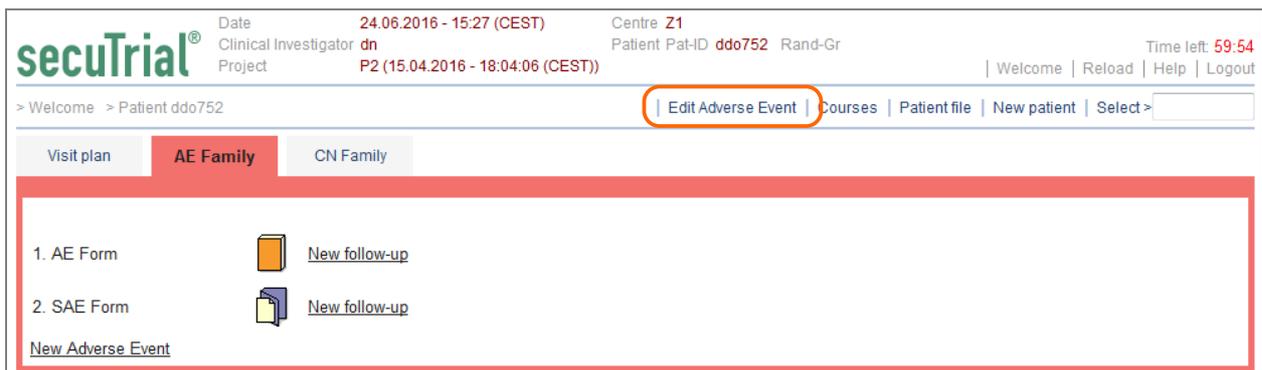
Fig. 6:   New menu option (highlighted) for editing adverse events.

On the editing page, the adverse event date and the follow-up examination dates are listed for all adverse events and can be edited there. In the upper area of the screen, the editing history can be displayed and hidden. If the participant only has the right to view the history, only the history will be displayed on this page.

Fig. 7:   Editing page (excerpt) for adverse events with history displayed.

Changing AE numbering (DC)   #8178

If the project has been configured so that adverse events can also be created in non-chronological order, when changing AE creation dates, the numbering of the altered chronological order can also be adjusted (AEs are normally numbered in the order they were created). An "Adjust numbering" checkbox has been introduced for this purpose above the date fields. The numbering can also be modified without changing the event or examination dates if the AEs were created in non-chronological order.

After changing the data or numbering, click on the "Check and continue" button for a summary of the performed changes. The modified date values will also be checked to ensure they are permitted. The examination date must always be after the event date and neither date is permitted to be in the future. If the changes are permitted, a reason must be entered in order to save the changes. A maximum of 200 characters are available for stating the reason.

Export table for AE / SAE date history (EST)

The history of edited AE / SAE data is exported in the export formats SAS, SPSS, CSV and TXT in a new "'atadverseevents" export table (abbreviation "atae"). It will only be exported if the Audit Trail has also been selected in the export options.

A precise description of the export table can be found in the "ExportFormats" documentation.

New features in FormEngine

6. Rule condition for text values in lookup entries (FB)   sT5.0-4.3, #8100

When defining rule conditions with reference to lookup items, it is now possible to select a specific text as a comparison value.

Fig. 8:   Definition of a comparison text for a lookup item.

Two new operators are now available as comparison operators for lookup items:

– contains
– does not contain

A comparison text must be entered for these operators. A maximum of 100 characters are available for this text.

When the rule is evaluated, it will be checked whether the text is contained anywhere in the text of the selected lookup table entry regardless of capital and lower case letters. Even in the case of extendable lookup tables, the comparison will always be performed for the selected entry, regardless whether the entry was pre-defined in FormBuilder or entered by a participant in DataCapture.

7. Hiding item options	sT5.0-4.4, #8101

Hiding item options makes it possible to exclude options that are no longer wanted from future use and, at the same time, all already saved forms where the otherwise excluded options had been selected will continue to be correctly displayed in full.

Hide radiobutton and popup label (FB)

Individual answer options for radiobuttons and popups can be hidden for items that have already been set to productive mode. Hiding options is done in the same way as hiding the entire item by clicking on the corresponding checkbox on the editing page of the item label group. The label will only be hidden in this specific item. A label hidden in an item can still be used as normal in a different item

Fig. 9:   Hiding individual labels in an option item.

Hidden labels are indicated in the implementation view of the form with a red dotted box around the individual answer option (for radiobuttons) or with a red "X" next to the entry in the label list (for popups).

Fig. 10:   Documentation of the configured "hidden" option in the implementation view for a radiobutton item.

Fig. 11:   Documentation of the configured "hidden" option in the implementation view for a popup item and a lookup table (see below).

Hiding entries in lookup tables (FB)

For lookup tables used in productive mode, individual entries can also be hidden from use in DataCapture. In the case of extendable lookup tables, only entries that have been entered in the FormBuilder can be hidden.
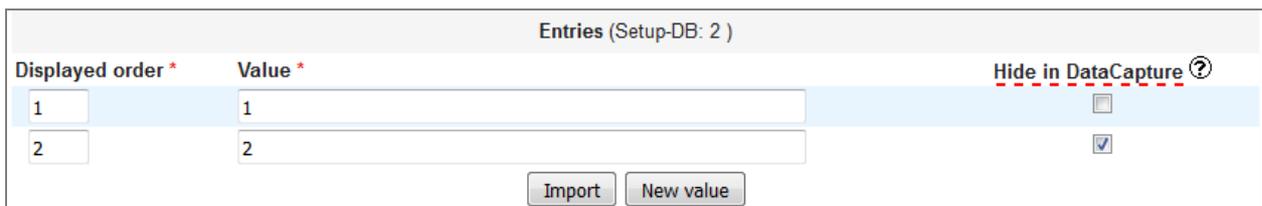
Fig. 12:   Hiding individual labels in a lookup table.

In the form implementation view, hidden lookup entries are likewise documented with a red "X" next to the entry in the list below the entry area of the form (see Fig. 11).

Treatment of hidden values in the form (DC)

In the form view in DataCapture, hidden options are distinguished according to use:

– Hidden value is currently saved

   The hidden value is displayed normally and can also be saved again.

– Hidden value is not currently saved (i.e. no value or other option saved)

   The hidden value is no longer displayed and it also cannot be saved.

When editing form data, if the participant switches from a currently saved hidden value to a value that has not been hidden and then saves the form, the hidden value can no longer be selected the next time the form data is edited.

Marking of hidden values in the audit trail (DC)

In the audit trail of the form, all saved values that have been configured as "hidden" will be highlighted with a dotted box. This is the same marking that is used for hidden items of questions, however for hidden values only the value itself is highlighted.

New table for hidden entries in the project description (EST)   #8278

In the form (mnp) tables all values are exported exactly as they have been saved. There is no distinction here between normal and hidden options.

To indicate hidden options, when the export option "Project setup" is selected, a new *deactivatedcodes* table (abbreviated name: *dc*) is exported. This contains all options from radiobuttons, popup and lookup

items marked as "hidden" with details of the project version since the entry was first hidden. In the SAS format, all hidden options from the entire project setup are exported. In other formats, only the options that actually contain data from the exported forms are exported.

A detailed description of this table can be found in the documentation on "Export formats".

8. Query reminder messages	sT5.0-2, #6950

This function can be used to send messages to remind the recipient about queries that have not yet been answered or closed.

Configuration in the project (FB)

The query reminder messages are configured in the project setup as project messages. Two new triggering events have been introduced for this purpose:

– Reminder: Query asked

    With this trigger either a new query has been created or there is an unanswered query.

– Reminder: Query answered

    This trigger means that a query has been answered but the answer has not yet been evaluated. The query still needs to be closed.

When selecting one of these triggers, the timeframe of the message must be configured. Enter the number of days after the last query to specify the start and end of the message period and enter the message interval in days.

Internal title: *	Query Reminder
Notification at ...: *	Reminder: Query asked ▾ 🕒

Messaging Period

Start *	1	day after last query entry
End *	5	days after last query entry
Interval (days) *	1 ?	

Fig. 13:   Area for configuring the message period for query reminder message.

The rest of the message configuration is the same as other project message. Multiple different reminder messages can also be defined for the same trigger.

Dispatch (AT)

The query reminder messages are evaluated and sent in the AdminTool of the respective area (setup / productive) in the background. For the messages to be dispatched, the relevant recipients must first be specified in the "Resources" area of the AdminTool.

The messages will be sent for each project at the time configured for bundled message dispatch.

Miscellaneous

9. Adding metadata to the export (EST)	sT5.0-4.1, #8098

For the export formats SAS, SPSS, CSV and TXT, there is now a new option for the patient metadata and structural information which is to be added into all patient-related tables. This comprises the following information:

Patient:

– Pseudonyms
– Centre
– Creation information (entry date, participant)
– Randomization

Structure:

– Visit (Label, No., ID)
– Adverse event examination (Date, No., ID)

The project definition and the options selected in the "Included data" section determine which metadata are repeated.

Metadata can be added to the following tables:

– `casenode` (only repetition of the column `mnpctrname`)
– `mnp... / atmnp`
– `emp... / atemnp`
– `queries`
– `comments`
– `sdv / atsdv`
– `miv / atmiv`
– `images`

Changes to the table structure

The "visitstartdate" column has been renamed as "mnpvisstartdate" to avoid name conflicts when repeating metadata in form tables.

In the casenode tables, for blinded studies two different columns are exported for the randomization number (suffix "no") and randomization group (suffix "gr"). Depending on existing or selected blinding, either only the "no" column (everything blinded) or both columns are exported.

The names of the randomization information columns have also been extended with the prefix "mnp".

Extended project setup functions

The "question" and "item" tables with the setup description have been extended. In the "question" table, the form name and the form table name are repeated.

In the "item" table, the main information about the superordinate question and table is repeated. Furthermore, as a new function, the item type and the unit text / the additional text next to the entry field are exported.

A new "deactivatedcodes" table lists all hidden project options (see: 7. Hiding item options sT5.0-4.4, #8101).

Note: A detailed description of all added and modified columns can be found in the current "Export Formats" documentation.

10. Filter icon report (DC)	sT5.0-4.5, #8102, #8356

For icon reports a new option for filtering the displayed data has been introduced. It is now possible to filter according to individual forms and according to the characteristic values of different form status or summarised form status.

This new filter can be shown in additional area below where the different form statuses are usually displayed.

Note: All filters will only take effect after clicking on the "Apply" button! By clicking on the "Reset" button, the filter can be reset to the original status.

Fig. 14:   Icon report with expanded filter area, but without additional filtering.

The new filter works in different ways:

–   Filtering of summarised data

When an individual form is selected, only the status of this form will be taken into account for all other options. This is indicated in the icon by an form icon instead of the otherwise used form family icon.

–   Filtering of displayed sums

When filtering by a specific form status or summarised form status, only the icons are displayed for which the field for the filtered status has been selected in the summarised status. For example, if the data is filtered by an individual form after the completion status "complete" without filtering for a single form, only the icons for the visits in which the summarised status of all forms of the visit is "complete" will be displayed. An individual, completely filled in form in this visit is not enough for it to be displayed.

–   Filtering of displayed patients

If not a single filter criterion is filled for a patient, the patient will no longer be displayed (see Fig. 15).

Fig. 15:   Icon report filtered according to the completion status "partial" of an individual form.

The filtering does not change the displayed columns. All existing visits are displayed, even if the filter criteria are only fulfilled in just one visit.

The previously existing displayed status filter (upper selection) remains unchanged as a function. It only changes the type of displayed icon, while the new filter can also prevent whole icons or patients from

being displayed. This old filter likewise only takes effect after clicking on the "Apply" button. It can be be reset to the original status via the "Reset" button.

View individual form   #8354

If the icon report is filtered according to an individual form, the form can also be directly viewed via the report by clicking on the form icon.

11. Automatic deletion of temporary files (CAT)   #7374

When the CustomerAdminTool is launched, all temporary files in the configured, temporary folders of the secuTrial® installation which were last edited more than one day ago are deleted.

12. SDV editing (DC)

Selecting "Not done" for entire form   #6379

When performing Source Data Verification (=SDV) for the entire form, a complete visit or the entire patient, the status "not done" can now also be selected if you want to immediately set the status for all edited data.

For all visible items in the forms (see below), an entry will then be explicitly created in the SDV table with the selected status, even if this status is "not done".

SDV and hidden items

When calculating the summarised status of a form, all hidden items will no longer be taken into account.

Vice-versa, the SDV entry of all items hidden at the time of calculation will be automatically deleted, which will reset the SDV status to "not done". If this automatic resetting changes the SDV status of an item which was previous marked as "verified" or the summarised status of the entire form, this will trigger a "SDV modified" message. However, this will only happen if such a message has been defined for the project.

Note: In previous secuTrial® versions, the automatic reset changed the status of the existing SDV entry to "not done". The new behaviour is now more logical, as this resetting is not explicitly performed by the triggering participant.

This correction to the SDV calculation is only performed if the form is edited again; editing here is considered to be setting SDV, normal data editing or data changed following a query. In contrast, when a review is created or a revalidation is performed, no adjustment is made to the SDV status.

The deletion of the SDV entries is also displayed in the overall SDV history of the form as a change to "not done". In the case of individual SDV popups, only the existing SDV entries for the respective item are shown. An automatic reset therefore cannot be listed there.

SDV for DB dummy item   #8270

An entry into the numeric field of a unit group is saved as a directly entered value in the otherwise not displayed DB dummy-type item if such an item has been created in the unit group. In the past, SDV was only set for the DB dummy field if this was edited for the entire form.

Now, the DB dummy item is always edited together with the numeric field. In DataCapture you cannot see the status for this item. Only if an export is performed is the entry exported for both fields. These should then always have the same settings, however there may be difference for older entries.

13. Java Version   #8251

This secuTrial® version can be operated with both Java 1.7 and Java 1.8.

Optimized user interface

Save notice on form page (DC)   **#8365**

After saving a form, the user is shown a save notice together with further navigation options. In the past, this view was displayed on a seperate page.

The save notice is now displayed in an overlay in front of the form that has just been edited. In the overlay the navigation options are shown with the choice of the next possible forms. The previously edited form is displayed underneath in a non-editable view in a darkened format (see Fig. 16).

If it is necessary to enter an e-signature in order to save the form, this will also be displayed in an overlay in front of the form that has just been edited. If necessary, all subsequent, frozen or released forms will be listed in the overlay for e-signature (see Fig. 17). After successfully entering the e-signature, the above-described save notice will be displayed.
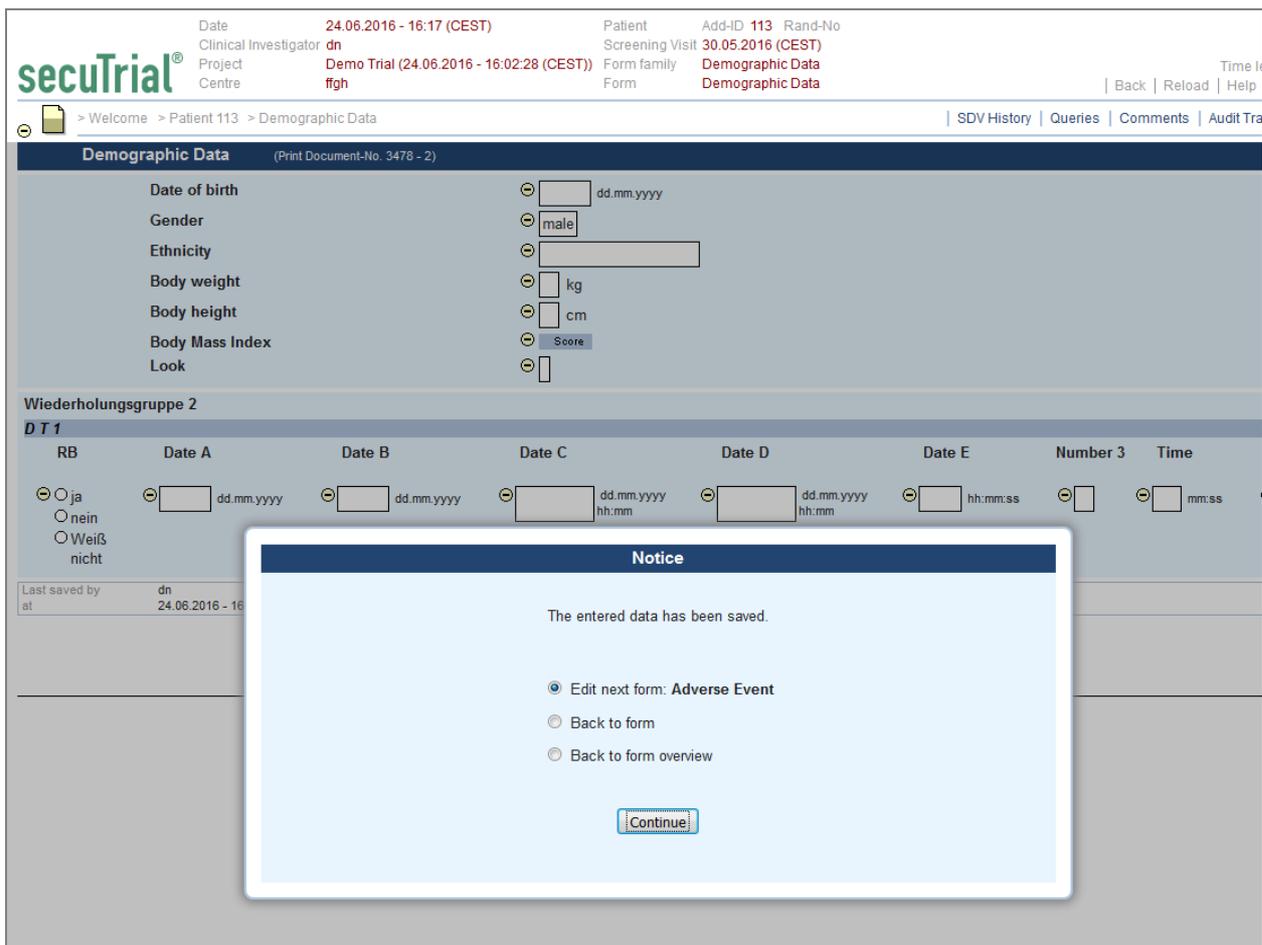
Fig. 16:   Save notice as an overlay in front of the form that has just been edited.

Fig. 17:   Entry of the e-signature in the overlay in front of the form that has just been edited.

Import (DC)   #8068

After performing a mass or multi-mass import, no "Cancel" button is shown now. This makes the user interface clearer.

Edit patient login (DC, AT)   #7749

When editing the patient login, the role is already pre-selected if there is only one role. It is no longer necessary to additionally click on an "Assign" button to edit the login password.

Display sorting order in lists (AT, CAT)   #3769, 8298

In the AdminTool and CustomerAdminTool many overview pages can be sorted according to the properties of the listed objects. This is done by clicking on the headings. The list will then be sorted by the respective property in ascending or descending order (if you click again).

The current sorting order is indicated next to the headings by a triangle pointing upwards or downwards.

Download design logo (AT)   #5776

For a customer area or a project, a specific logo can be uploaded in the design. The currently used logo is displayed on the design editing page in a preview for the login (large logo) and menu area (small logo).

The displayed logo can once again be downloaded via a button and saved locally (since the use of the right-hand mouse button is prevented by Javascript, this function was not available in the browser as otherwise standard.)

Participant page layout (AT)   #7551

On the editing page for a participant, three different areas can be expanded for participant properties. These areas have now been given headings that better summarise the function of the editable properties underneath.

Display rule references after being set to productive mode (FB)   #8099

On the editing pages for the different levels of the project setup, in the overview list of the next lower level elements, the "Delete" is not displayed if either the element cannot be deleted because the project has already been set to productive mode or the element cannot be deleted due to rule references outside of this area.

The link to rule references is now also displayed for elements that cannot be deleted because the project has already been set to productive mode. As a result, the performance when displaying the setup of these projects may be slightly diminished.

Dossier layout (FB)   #7542

The restriction of the page width in the downloaded project dossier has been removed. The dossier now uses the full page width available in the browser. When printing the dossier, please therefore check that the full contents of the page is included in the print out.

Cursor in the text field for new lookup entries (FB)   #8063

When creating new lookup entries in a new lookup table, after clicking on the "New entry" button the cursor automatically appears in the text field of the new entry.

Configurable number of displayed list elements (EST)   #6469

In the ExportSearchTool, the number of list elements displayed on the "Download" and "History" pages can be configured by clicking on the text "Page 1 of 2". The setting will be applied for the duration of the session.

Updated Excel version (DC / FB)   #8333

The library which is used for generating the downloadable "real" Excel files for various functions has been updated. It is now also possible to create Excel files in the newer Excel2007 format (the previous file format was Excel97). However, to ensure the greatest possible downwards compatibility, the new file format is not used for all areas.

When creating Excel files in DataCapture for SQL reports with more than 255 columns, the new file format Excel2007 is always automatically generated, as it allows a much greater number of columns in one file.

When creating dataset tables in the FormBuilder, you can select which file format should be generated. If you are using Excel2007, It is not necessary to subdivide the data into individual files because this file format is much better at handling the amount of formatting contained in the dataset table.

Avoiding page reloads (AT)   #8309

In the AdminTool the page behaviour on the resource overview page and the role editing page has been changed. When individual resources are selected for editing, the page is no longer reloaded. When selecting form rights from the dropdown list, the role editing page is likewise no longer reloaded. As a result, the rights are no longer automatically assigned to all of the forms listed below. This process is now only executed after clicking on the "Save" button.

Note: When editing the form rights, the selected form rights should be assigned before changing projects by clicking on the "Save" button.

Bottom menu bar structure (AT)   #8368

The buttons in the bottom menu bar on the list and editing pages in the AdminTool are now arranged in a maximum of three areas:

– Editing (Back, Save, New Object)
– Miscellaneous (Assignments, Exports, Logs, Preview)
– Delete (Delete single objects, Clean up)

These sections are separated by a larger gap between the buttons.
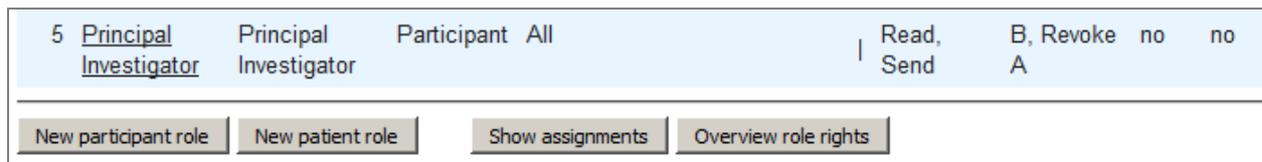
Fig. 18:   New bottom menu bar structure on the role overview page.
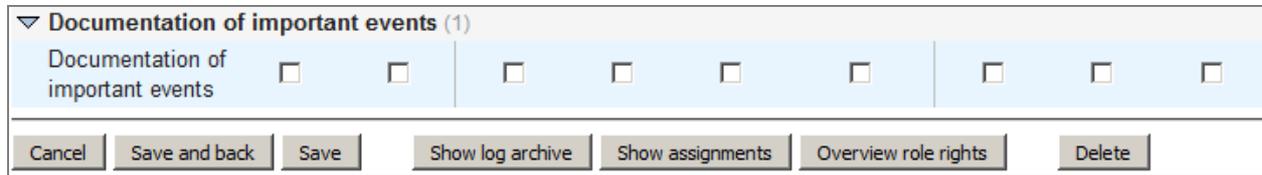
Fig. 19:   New bottom menu bar structure on the role editing page.

Note: Due to the new structure, on the participant overview page the buttons for importing (=Create new) and exporting participants have been swapped. On the patient overview page the "Print" button has been moved to the middle area.

Internal restructuring

Automatic message dispatch (CAT / AT)   #6950

The message dispatch functions that were previously performed in the background of the CustomerAdminTool are now performed in the background of the respective AdminTools. Therefore, there is no longer an update function for messages in the CustomerAdminTool. However, on the background page the number of messages currently waiting to be sent via the bundled message dispatch is still displayed.

Search page structure (EST)   #4265

In the search area of the ExportSearchTool, the previously used HTML frames for the status and menu sections have been replaced with CSS formatting.

Fixed issues

CustomerAdminTool

#8279   The automatic import of CSV files did not work if the CSV file had a file name with fewer than 3 characters (without file extension).

This issue has been fixed. The file name is automatically extended if necessary.

FormBuilder

#6832   The configuration option "Hide in DataCapture" was also displayed for sub-forms even though entries for this form type are not evaluated (hiding sub-forms can be configured by hiding the used repetition group).

This configuration option is no longer displayed for sub-forms.

#7569   When copying a form or form element, if copying was initially not possible due to an error message, e.g. because the entered form name is too long, then all other changes on the copy page were also reset to the original value of the copy template.

This issue has been fixed. If an error message is displayed during the copying process, any changes that have been made are retained. Only if the copy template is changed will all entries be changed to the values in the template.

#7735   The rule "Hide if …" could not be set for layout dummy-type items.

This rule can now also be defined for this item type.

#8192   When accessing the search preview of a form, an error (exception) occurred if the form included a sub-form containing an IASVertRBMatrix or an IASHorizUnitGroup in which a hide rule was defined for an item.

This issue has been fixed.

#8230   On the editing page of a project visit plan, the related rules for the definition of the treatment arm are displayed for the treatment arms. An error (exception) occurred when the button to go to the rule definition was clicked.

This issue has been fixed.

#8375   In the XML export of a project setup or of SQL reports, all tab stops contained within free text fields were removed. This was also the case for the SELECT statement entered in free SQL reports. If the tabs were the only separators between elements in the statement, this could modify the definition of the statement when reimporting the export.

This issue has been fixed. Tabs in all text entries in the project setup are now retained in the XML setup export and reimport.

AdminTool

#8281   The reminder messages for empty visits could be sent multiple times on one day if secuTrial® was restarted after the start point configured in the project for bundled message dispatch. This resulted in duplicated dispatch at the next bundled message dispatch interval.

This issue has been fixed. Reminder messages are now only sent once a day (see also: Internal restructuring, Automatic message dispatch (CAT / AT) #6950).

#8283   When selecting a resource via checkbox for mass editing, the resource overview page is reloaded. The page always jumped to the top of the page.

This issue has been fixed. When the page is reloaded the original position is now always displayed.

#8287   When configuring bundled message dispatch on the project editing page, the general time zone of the server was used for the start point instead of the time zone configured in the secuTrial® installation. This could result in differences from the actually used start point (displayed time for messages in the resources overview).

This issue has been fixed. When editing the start point, the time zone configured for the secuTrial® installation is used.

#8323   When creating a new centre, the project selected on the centre overview page was not automatically used. The project had to be selected again on the centre editing page.

This issue has been fixed. The previously selected project is now used.

#8377   On the page for cleaning up participants, certain texts were not always displayed in the otherwise used language.

This issue has been fixed.

#8376, #8378   Some of the page titles contained a spelling mistake and were labelled inconsistently.

The page titles have been corrected.

DataCapture

#3979   Some of the additionally opened browser windows for various functions did not yet use the otherwise usual layout for the general menu functions.

The layout has been standardised in all additional browser windows of the secuTrial® DataCapture tool.

#4532   If an error is made when entering the login page URL for patient self-documentation (e.g. invalid customer ID), the general customer selection page is displayed (if permitted by the installation configuration). If the patient then selected the correct customer from the list, the participant login page was displayed instead of the patient login page. It was not possible to login even if the correct login data was entered.

This issue has been fixed. In such cases the patient is redirected from the customer selection page to the patient login page.

#6089   When entering the entry date for a new patient it was possible to enter the day and month with only single digit numbers.

When the entry date is entered now, single digit day and month entries are now automatically preceded by a zero.

#7859   The SDV summarised calculation of forms with hidden questions or items was not correct.

This issue has been fixed.

Note: For this error please read the detailed description under 12. SDV editing (DC)!

#8246   If a "Freeze follow-up form if…" rule is fulfilled in a form and either the form itself or the freeze process requires a signature, all subsequent forms to be frozen are listed when the e-signature is entered. Here, forms were also listed for which double data entry (DDE) is necessary and which cannot be frozen via this rule.

This issue has been fixed. Only forms that can actually be frozen are now listed.

#8269   When opening the SDV editing popup for the number and unit item in a unit group, not only was the saved SDV status for the item displayed but also the one for the previous additional item. However, setting and saving an SDV status for the intended item was nevertheless correctly carried out.

This issue has been fixed.

#8333   The Excel file for an SQL report could not be downloaded (exception) if more than 255 columns were displayed in the report.

This issue has been fixed. For SQL reports with more than 255 columns, an Excel2007 format file is now generated (see also: Updated Excel version (DC / FB) #8333).

#8357   When reloading DataCapture to refresh all data, logos which had been reset or modified were not updated as well. The modified logo was only correctly displayed after logging out and logging in again.

This issue has been fixed.

ExportSearchTool

#7733   When configuring a new export, you can select all required centres of a project in the upper area. When the page is opened for the first time, all centres are automatically selected for the uppermost project which is selected by default. If the selected project was changed, only the same number of centres which was selected in the previous project was selected rather than all centres again.

This issue has been fixed. When the project selected for export is changed, all centres of the project (which are available to the participant) are automatically selected. The selection can then be manually changed.

#8239   In the "miv" table ("Missing Values" function values) of the export, there was no column for entering the "mnppusid" (=patient ID as the data editing author for patient reported outcome). The use of the MV function together with the PRO could therefore result in entries in the table without an entered author.

This issue has been fixed. When using the PRO function, the patient is listed as the author in an additional "mnppusid" column as applicable.

#8243   In the "atcvp" table, the table description in SAS did not match the exported data columns if the structural information for the export had been deselected for export. In the description the visit information data was then missing, although this information was contained in the data.

This issue has been fixed. Deselecting structural information now has no effect on the exported data and table description in the "atcvp" table.

Installation script

#8114   The update still always contained an SQL script for the update to secuTrial® version 4.1.

         This SQL script no longer exists now.

Fixed issues from 4.9

FormBuilder

#8311   When copying a "Layout Dummy"-type item, the additional label text could not be edited; it was not displayed in the template or in the new item.

         This issue has been fixed. The label is now displayed for layout dummy items in an additional row during the copying process.

#8312   When the form preview was updated, changes in a checkbox matrix were not adopted.

         This issue has been fixed. When updating, any data previously entered in the preview or any created repetitions of sub-forms are also deleted again or reset.

#8355   The "Hide if…" rule could be defined multiple times for the same question or item. In the case of different rule conditions, this could mean that the displayed rule element could not be predicted if one rule was fulfilled and the other rule was not fulfilled.

         The "Hide if…" rule can now only be applied once to an distinct item or question. Rules that have been created multiple times will be displayed as errors during project validation. The rules are evaluated in DataCapture exactly as before.

         Note: We recommend checking all projects for duplicate created rules and consolidating these rules with logically linked conditions in a single rule!

DataCapture

#8303   When sending messages from forms, values from form items can be integrated into the messages. If scores were included, the score item units were appended twice to the calculated value.

         This issue has been fixed.

#8330   When creating a new adverse event, if neither the event date nor the examination date was entered, the error message "Please enter both dates." was displayed twice.

         The error message is now only displayed once.

#8335   The mass import in an individual form could not be successfully performed if the function "Patient in multiple centres" was used, the patient was entered into a new centre by the participant, the new centre was selected for the import and the participant was also not additionally assigned to the home centre (=centre when creating the patient). The import data analysis was initially performed successfully, however the execution of the import was rejected with the error message "Error (not imported). No access rights to patient.".

         This issue has been fixed. During the mass import in an individual form, the access rights to the centre selected for the import are now always checked. Any centres entered in the file (according to the definition in the import format) are then ignored. If "all centres" is selected, either the centre entered in the data or the home centre of the patient will be use to check the rights for the import.

#8349   During a mass import in an form, all form datasets that cannot be imported due to the general configuration (e.g. because the form is not displayed in the visit entered in the import) are listed in a separate section of the error details description. Form names with special characters were not correctly displayed here.

         This issue has been fixed.

Issues fixed during development

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

#4265, #8062, #8064, #8083, #8084, #8085, #8107, #8111, #8133, #8134, #8144, #8147, #8149, #8150, #8153, #8154, #8156, #8157, #8159, #8160, #8161, #8162, #8163, #8164, #8167, #8168, #8169, #8174, #8176, #8177, #8180, #8181, #8183, #8184, #8185, #8186, #8189, #8191, #8193, #8194, #8195, #8196, #8197, #8198, #8199, #8200, #8201, #8202, #8204, #8205, #8210, #8211, #8212, #8216, #8217, #8219, #8221, #8222, #8223, #8224, #8225, #8226, #8228, #8229, #8231, #8233, #8234, #8235, #8237, #8238, #8240, #8241, #8242, #8248, #8249, #8250, #8256, #8260, #8263, #8264, #8271, #8272, #8274, #8275, #8276, #8277, #8280, #8284, #8285, #8286, #8289, #8290, #8291, #8292, #8294, #8295, #8296, #8297, #8301, #8302, #8322, #8326, #8328, #8342, #8343, #8344, #8345, #8358, #8359, #8370, #8371

Deployment

Database

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

Java Version   #8251

This secuTrial® version can be operated with both Java 1.7 and Java 1.8.

secuTrial® 5.0.1.12 (inkl. 5.0.1.11)

Released 20/04/2016

New functions

No new features implemented.

Fixed issues

All Tools

#8381, #8393, #8465, #8498   In some English labels and (error) messages of different functions were spelling errors or inconsistencies in the wording.

The English text entries have been corrected.

FormBuilder

#8380   By now the rule "hide, if .." can also be created on Layout-dummy-items. Such rule was however deleted automatically, when the item editing page itself was saved. (To create a rule only the rule-editing page must be saved.)

The issue has been fixed.

#8398   The rule "hide, if .." could no longer be copied. The rule was offered as a copy-template first, but the selection could not be saved afterwards. Only the error message "Please select a rule." was shown and the hide-rule was then no longer included in the template-list.

The issue has been fixed. The rule "hide, if …" can also by copying only created once per item or question (see #8355).

#8479   Items and rule on items could no longer be copied (exception).

The issue has been fixed.

#8485   In the implementation form view incomplete or invalid rule references are marked by a red hash sign. This sign was missing when a invalid sub-form was referenced in a sub-form rule. (Such invalid reference is causing an exception during data entry in DataCapture.)

The markup sign for invalid rules in the implementation view is now also shown for invalid sub-form references in sub-form rules.

AdminTool

#8506   In the design-preview the button "new patient" was not using the same label entry as in the DataCapture. Project-specific changes of this label were therefore not shown in the preview.

Now the same label-entry as for the DataCapture is now used for the design-preview.

DataCapture

#8392   When the SDV and the e-signature function was configured for a project the signature for the first form save always became invalid at the next form save. It was irrelevant for what action the first and second form save was done (e.g. data entry or comment). This error was an aftereffect of the changes in SDV editing in Version 5.0.1.

The issue has been fixed.

Note: Already invalid e-signatures will not become valid by this correction!

#8451   When using the DEC workflow a reason must be supplied when modifying the data after a query was set. When a signature is additionally required for this form save the signature fields are now displayed in an overlay above the form. When the overly was shown the focus (cursor) remained

mistakenly at first in the non-editable reason text field. So the reason could have been changed unintentionally when entering the login credentials for the e-signature.

The issue has been fixed.

#8493   If a date item was used in the condition for a hide-rule the hiding was not triggered, if the date was not entered manually but by using the calendar date picker.

The issue has been fixed.

#8494   A form could not be saved by a patient during the patient reported outcome workflow (exception), when the form contained a repetition group and the SDV function was activated for the project.

The issue has been fixed.

#8534   In rare cases the validation report could not be shown (exception). This could happen, when forms or patients had been deleted in the project.

The issue has been fixed.

ExportSearchTool

#8555   During export it could happen that a participant could export data of a centre where the participant was not assigned. This error only happens if the participant was assigned to multiple projects, the project selection was changed, the participant was only assigned to a single centre in the then selected project and the export format type was changed before starting the export.

The issue has been fixed.

Fixed issues from 4.9.1

FormBuilder

#8374   On the visit plan editing page an error (exception) occurred, when the link to change to the visit plan arm rule was clicked.

The issue has been fixed.

#8564   When editing a rule condition no distinct visit could be selected for the comparison value (exception).

The issue has been fixed.

DataCapture

#8505   In the discrepancies report the patients were always sorted according to the Pat-ID even if that pseudonym was not displayed in the project or report.

The issue has been fixed. The patients are now sorted according the pseudonym displayed in the report.

#8507   In the overview page for reports and statistics the projects were listed in random order.

The projects are now listed alphabetically according project name.

#8508   When a project configuration allows that a patient is assigned to multiple centres and that visits can be owned by the creating centre, the discrepancies report could inititaly show some discrepancies of forms that the current participant was not allowed to see according his role rights. After the first filtering of the report by any item these discrepances were than correcly filtered out from display too.

The issue has been fixed.

#8510   In RepetitionGroups the reverse display of the repetitions can be configured. If the SDV or MV function was used and a new repetition entry was created in reverse order the SDV and MV values were used from the previosly last repetition and applied to the new repetition. By this it could happen that the new created entries were all set immediatly to SDV-"verified".

The issue has been fixed.

ExportSearchTool

#8468   In the SPSS export format box, the VALUE LABEL for the *visitplan* table was not correctly entered in the sps definition file. Instead of the possible numerical values for the *visittype* column, the Java name of the visit type had been entered.

This issue has been fixed.

Deployment

No special handling necessary.

secuTrial® 5.0.1.13

Released 25/05/2016

New features

DataCapture user interface in Greek   #8476

The user interface of the DataCapture has been translated into Greek. In order to use this language the application configuration has to be extended (see: Deployment: Configuration).

Fixes issues

FormBuilder

#8499   During the definition of mapping for import formats it was possible to create mappings for DB-Dummy-Items in Unitgroup question components. An import into such items was nevertheless not possible and always rejected with a format error.

Import mappings can no longer be created for DB-Dummy-Items. An import into these items is not intended.

#8576   When downloading the project dossier in one of the ISO character sets the Greek characters cannot be displayed. When using a Windows-PC the ISO-8859-15 character set has been preselected.

In FormBuilder the preselection for all downloads with selectable character set has been set to UTF-8.

#8622   The copy of an hide-rule was not possible, when that rule was the only rule on the template form.

The issue has been fixed.

Fixed issues from 4.9.1

FormBuilder

#8566   When two (or more) hide rule has previously been created on an item the item itself (e. g. the item label) was no longer editable. The error message "There is more than one 'Hide' rule defined." was always displayed. It was neither impossible to delete one of the hide-rules. As a workaround one of the rules could be changed into another rule type (e.g. "input not necessary") after all rule conditions had been deleted.

The issue has been fixed.

Fixed issues from 4.8.0

DataCapture

#3472   The code signing certificate for the DICOM applett was expired.

The certificate has been renewed.

Deployment

Configuration

In order to use the Greek user interface for the DataCapture the list of all usable languages in the *.secuSuite.cfg files has to be extended with "el" (ISO 639 abbreviation for Greek):

```
available_languages = de, en, fr, it, pl, es, sv, el
```

secuTrial® 5.0.1.15 (inkl. 5.0.1.14)

Released 09/06/2016

New functions

Configuration Webservice Session-Timeout   #8659

The length until the timeout of a session created by a Webservice was previously fixed to 1 minute.

Der Session-Timout kann jetzt über den Startparameter "-DSRTWebServiceSessionTimeout=60" (Angabe in Sekunden) für das jeweilige DataCapture konfiguriert werden (siehe auch).

The session timeout is now configurable with the start parameter '-DSRTWebServiceSessionTimeout=60' (specification in seconds) for the respective DataCapture (see also: Deployment: WOMonitor).

Direct login via hand-over of valid session-ID to DataCapture   #8658

When after a successful Webservice authentification in secuTrial® a valid session has been created the returned session-ID can now be used to create a new URL that leads directly to the Welcome page of the DataCapture without the need for another login. The respective, valid session-ID has to be appended to the following URL (text in square brackets and name of the DataCapture has to be replaced):

> [Server-URL]/apps/WebObjects/ST21-setup-DataCapture.woa/wa/login?wosid=[Session-ID]

If the session-ID is invalid, e.g. because the session already timed-out, the participant will be forwarded to the corresponding login page of the customer area. If the customer area could not be identified, the customer-selection page, resp. the notice page for the entering the cusomer-URL will be shown instead.

Fixed issues

Fixed issues during development

The following issue was discovered in the development process and fixed: #8666

Deployment

WOMonitor

To configure the session timeout-length of the Webservices the following start parameter has to be added in the field "Additional Arguments" of the wanted DataCapture:

Webservice-Session timeout (seconds):   `-DSRTWebServiceSessionTimeout=60`

secuTrial® 5.0.1.19 (incl. 5.0.1.16–18)	iAS
Released 16/06/2016	

New functions

No new functions implemented.

Fixed issues

All Tools

#8504   When using the american display for date entry fields (sequence yyyy/MM/dd, configurable per configuration file for the complete installation) the calendar date picker in some places mixes up the date parts (entering the day into the year part and vice-versa). The date was correctly transferred in the DataCapture form date item, but incorrectly when creating a new patient or a new visit.

The issue has been fixed.

FormBuilder

#8639   When only multiple single forms were imported via the project setup the previous sequence of the forms was not respected but the forms were appened to the existing forms in the form family in random order.

The issue has been fixed.

#8651   When creating a new form it was possible to specifiy the prefix part "mnp"+DB schema name as the additional table name. During save the duplication was removed and the prefix only was used as the table name.

The issue has been fixed. Already created forms whith similar names should not be used, because this could at last result in no identifying name at all when the export tries to shorten the table name.

#8672   The copying of a question rule was not possible (exception when clicking on the copy-button).

The issue has been fixed.

DataCapture

#8644   When (simple, extendable or hierarchical related) lookup tables were used within a sub-form repetition, and in already stored form with multiple repetitions some initial repetitions were deleted at the top of the display, the selected lookup values in the remaining repetitions were no longer correctly displayed. Either no selection was displayed at all or the selection of the deleted repetitions were transferred to the remaining repetitions.

The issue has been fixed.

#8647   It can be configured per project that the AE / SAE workflow can be selected by user-preselection and the entry of the AE, resp. SAE date can be skipped. If a new follow-up was created for an SAE event in this configuration instead of the first SAE form the first AE form was opened. The form could be filled and saved but was not displayed in the form overview afterwards.

The issue has been fixed. Already filled AE forms in an SAE will still not be shown in the patient's form overview. But this data are included in the export.

#8652   If a participant made multiple new entries in an extendable lookup table all of these new entries were saved during form save even if the participant can select only one new value for the respective form item.

The issue has been fixed. During form save only that new-entries are created which are selected at last for the respective lookup item.

#8680   The direct login with a valid session-ID via the login-URL (see #8658) did not work always. Often the error page with the message "session hijacking" was displayed.

The issue has been fixed.

ExportSearchTool

#8683   If a search form contained date items the calendar date picker was displayed for these items. The selected date value was not transferred to the corresponding form item.

The issue has been fixed.

Fixed issues during development

The following issues were discovered in the development process and fixed: #8681, #8686, #8687

Deployment

No special handling necessary.

secuTrial® 5.0.1.20

Released 13/07/2016

New functions

No new functions implemented.

Fixed issues

DataCapture

#8647   It can be configured per project that the AE / SAE workflow can be selected by user-preselection. If a new follow-up was created for an SAE event and the examination date has to be entered first, instead of the first SAE form the first AE form was opened. The form could be filled and saved but was not displayed in the form overview afterwards.

The issue has been fixed. Already filled AE forms in an SAE will still not be shown in the patient's form overview. But this data are included in the export.

#8719   For forms the processing option "print" can be configured in the FormBuilder. In DataCapture instead of a "Save" button a "Save+Print" button will then be displayed. When saving such a form the form print view was no longer automatically opened. The form could although be printed correctly via the "Print" option in the upper menu bar.

The issue has been fixed.

#8749   In the definition of a rule condition for a text item the new operators "contains" or "contains not" can be specified to test the entered text for a fixed text part. The evalution of such rule conditions did not work correctly when no text at all was entered in the text item.

The issue has been fixed. If no text has been entered the check for "contains" as well as "contains not" will always evaluate to "false".

ExportSearchTool

#8730, #8754   In SAS export format the column definitions (format) and the column labels in the adverse event audit trail table 'atadverseevent' (short: 'atae') was partly incorrect. The documentation of the date columns 'olddate' and 'newdate' in the ExportFormat was incorrect too, these date values are exported as date with time and not as date only.

The issues have been fixed and the ExportFormat documentation corrected.

#8733   In the SAS export format the specified record length of the casenode table was too short if the project used any randomizations. And the record length in the forms and items table was too short either, if the project used the DDE function. This could cut off the data contents of the tables when importing these export into SAS.

The issue has been fixed.

Deployment

No special handling necessary.

secuTrial® 5.0.1.21

Released 04/08/2016

New functions

No new functions implemented.

Fixed issues

CustomerAdminTool

#8793   If an error occurred during a background process, e.g. the generation of statistics or the bundled message dispatch, an e-mail could be sent to an administrator address that has been set in the secuTrial® configuration file. This e-mail contained the name of the triggering application but not the name of the server. The allocation of the problem could therefore become difficult if there were multiple secuTrial® installations.

The e-mail subject has been extended with the server name (deployment-URL).

AdminTool

#8789   The german help text for patient import contained a content-related error.

The german help text has been corrected.

#8795   In the design properties an URL can be specified that will be opened in the DataCapture when clicking on the logo. If the URL was specified with the protocol "https" the URL was automatically additionaly prefixed with the standard protocol "http", resulting in an invalid URL.

The issue has been fixed. The URL can now be specified with both protocols, "http" or "https". If no protocoll is supplied the default protocol "http" is automatically added.

#8812   When importing patients it can be selected that the visits to be created are included in the import file. If the project's visit plan contained a visit repetition group, visits after the visit group could not be imported if the import did not create the maximal number of allowed group repetitions before.

The implementation has been changed. If the label of the visit (optional with additional visit number) is supplied in the import file, the visits are now identified directly by the visit label and repetitions of visit groups may be skipped. To identify the matching template for each visit included in the import all visit templates of the project are checked in the template's sequence and the visit label (including the visit number) is used to compare the visit labels of import and template. The first template with matching label is then used to create the visit. Only visits without visit arm can be created during patient import.

DataCapture

#8788   When importing data via the FormDataTransmission webservice all actions defined by the form are perfomed. This includes the sending of e-mails. If the patient's pseudonyms had been included in any of these webservice triggered messages these messages always contained the standard pseudonym names even if the pseudonym names had been changed in the respective design configuration.

The issue has been fixed.

#8797   The print display of the patient-inclusion form contains a text field in which all entries of the form are listed, separated by semicolons. If a project had been configured as "international", the centre's country has been included in this text field twice: once in a separated column before the centre and once added behind the centre's name, separated by a comma.

The issue has been resolved. For international projects the country is now included as a separate column behind the centre. If the centre does not have a country assigned, this column will be empty.

ExportSearchTool

#8783   When exporting in SAS format the table "deactivatedcodes" contained an invalid column definition for the column "versiondate" (wrong placed position). Therefore this table could not be imported into SAS successfully.

The issue has been fixed.

Fixed issues from 4.9.1

DataCapture

#8787   In the discrepancies report only discrepancies with the status "new" were displayed (aftereffect of the fix for #8508). Rejected discrepancies or discrepancies with queries were not longer listed.

The issue has been fixed. The initial filter still shows only "new" discrepancies but all rejected discrepancies or those with queries can be displayed by selection of the status filter.

Deployment

No special handling necessary.