

secuTrial® 5.1.1.7 – Release Notes

Based on Version 5.1.0.22



New Functions

Extended discrepancies workflow

sT5.2-6, #8746

The DTM workflow has been extended to enable discrepancies to be edited in different ways. These new features relate to editing in the discrepancy report; the importing of discrepancies remains unchanged.

New status "pending"

An additional "pending" status has been introduced to signalise that a final decision has not yet been made regarding the classification of a discrepancy. The status can be selected when individually editing a discrepancy.

As long as a discrepancy has not been transferred into a query, the status can be changed as many times as necessary. The following discrepancy status settings are now possible:

- new (imported)
- rejected (no real problem)
- pending (will be checked again later)
- query created
- resolved (query has been closed)
- check again (query has been closed with status "check again")

A discrepancy can be edited until it is assigned a query-related status. The status "resolved" and "check again" are automatically set when editing the query.

When discrepancies are imported again, entries identified as doublets will only be rejected if the discrepancy has the current status "check again".

Dcr-No. (Q)	Test-No.	Test-Date	Patient	Centre	Document-No.	Form	Item	Event	Last edited	Participant	Status
1	8	3	04.04.2017	vne074	Berlin	25	Bilder im Visitenformular - Lookup	2. visit	04.04.2017 - 11:27 (CEST)	Dipl. Biol. Susanne Schneider	new
2	7	3	04.04.2017	vne074	Berlin	9	Bilder im Visitenformular - Lookup	Screening	04.04.2017 - 14:14 (CEST)	Dipl. Biol. Susanne Schneider	pending
3	7	1	16.02.2017	vne074	Berlin	9	Bilder im Visitenformular - Lookup	Screening	04.04.2017 - 11:28 (CEST)	Dipl. Biol. Susanne Schneider	rejected
4	7	2	20.02.2017	vne074	Berlin	9	Bilder im Visitenformular - Lookup	Screening	24.03.2017 - 14:39 (CET)	Dipl. Biol. Susanne Schneider	rejected
"text: instruction" <input type="radio"/> new <input checked="" type="radio"/> reject <input type="radio"/> set pending <input type="radio"/> create query											
Comment text: instruction <input type="text"/> <input type="button" value="Save"/>											
5	13	3	04.04.2017	vne074	Berlin	25	Bilder im Visitenformular: Subform - Number	2. visit	04.04.2017 - 11:35 (CEST)	Dipl. Biol. Susanne Schneider	new
6	5 (#28)	1	16.02.2017	vne074	Berlin	13	Bilder im Visitenformular-2 - Neue Zahl	Screening	17.02.2017 - 19:32 (CET)	Dipl. Biol. Susanne Schneider	resolved
7	5 (#29)	2	20.02.2017	vne074	Berlin	13	Bilder im Visitenformular-2 - Neue Zahl	Screening	20.02.2017 - 14:19 (CET)	Dipl. Biol. Susanne Schneider	check again

Fig. 1: Excerpt from the discrepancy report with entry opened for editing.

Comments

A comment can now be added each time a discrepancy is edited (max. 1,000 characters). When the status is set to "pending", entering a comment is mandatory; for all other statuses it is optional. If a comment has been added, the comment field will be pre-filled with this text the next time that the discrepancy is opened for editing. The comment can be expanded or (depending on status) completely deleted.

If the status remains the same, it is also possible to just edit the comment. If neither the status nor the comment have been modified, there is no option to save.

The comment is displayed as an extension of the report in the column.

Test-Date	Patient	Centre	Document-No.	Form	Item	Event	Last edited	Participant	Status	Comment
04.04.2017	vne074	Berlin	14	Test - Text		Screening	04.04.2017 - 14:20 (CEST)	Dr. Ulrike Jonas	rejected	value is ok
04.04.2017	vne074	Berlin	11	Komponenten-Test - 2.0		Screening	04.04.2017 - 14:20 (CEST)	Dr. Ulrike Jonas	rejected	item has been hidden
04.04.2017	vne074	Berlin	18	Form 1 - 6.0		Screening	04.04.2017 - 14:19 (CEST)	Dr. Ulrike Jonas	query created	let investigator check value again
04.04.2017	vne074	Berlin	25	Bilder im Visitenformular: Subform - Number		2. visit	04.04.2017 - 14:18 (CEST)	Dipl. Biol. Susanne Schneider	new	better repeat the test
04.04.2017	vne074	Berlin	16	MV-Test: Subform - Number		Screening	04.04.2017 - 14:17 (CEST)	Dr. Ulrike Jonas	rejected	not necessary
04.04.2017	vne074	Berlin	9	Bilder im Visitenformular - Lookup		Screening	04.04.2017 - 14:14 (CEST)	Dipl. Biol. Susanne Schneider	pending	check later

Fig. 2: Excerpt from the discrepancies report with comments in the last column.

Audit Trail

In previous versions, only the most recent editing status was saved in the discrepancy. Now every editing step is logged in an audit trail.

In the report, the current status is shown for every discrepancy. Any previous editing steps can be displayed by clicking on the triangle next to the editing date.

Document-No.	Form	Item	Event	Last edited	Participant	Status	Comment
14	Test - Text		Screening	04.04.2017 - 14:20 (CEST) Dr. Ulrike Jonas 04.04.2017 - 11:27 (CEST) Dipl. Biol. Susanne Schneider	Dr. Ulrike Jonas	rejected	value is ok
11	Komponenten-Test - 2.0		Screening	04.04.2017 - 14:20 (CEST) Dr. Ulrike Jonas 04.04.2017 - 11:27 (CEST) Dipl. Biol. Susanne Schneider	Dr. Ulrike Jonas	rejected	item has been hidden
18	Form 1 - 6.0		Screening	04.04.2017 - 14:19 (CEST) Dr. Ulrike Jonas 04.04.2017 - 11:27 (CEST) Dipl. Biol. Susanne Schneider	Dr. Ulrike Jonas	query created	let investigator check value again
25	Bilder im Visitenformular: Subform - Number		2. visit	04.04.2017 - 14:18 (CEST) Dipl. Biol. Susanne Schneider 04.04.2017 - 11:35 (CEST) Dipl. Biol. Susanne Schneider 04.04.2017 - 11:27 (CEST) Dipl. Biol. Susanne Schneider	Dipl. Biol. Susanne Schneider	new	better repeat the test weiterer Kommentar
16	MV-Test: Subform - Number		Screening	04.04.2017 - 14:17 (CEST) Dr. Ulrike Jonas 04.04.2017 - 14:15 (CEST) Dipl. Biol. Susanne Schneider 04.04.2017 - 11:27 (CEST) Dipl. Biol. Susanne Schneider	Dr. Ulrike Jonas	rejected	not necessary check later

Fig. 3: Excerpt from the discrepancy report with audit trail entries opened for viewing.

Page-by-page display in the discrepancy report

#9221

Discrepancies are now displayed page by page in the report, initially with 100 entries per page. You can move from page to page using the navigation buttons in the title bar. The number of entries displayed per page can be changed for each session by clicking on the page display between the navigation buttons.

If one or more discrepancies are selected from a page for editing, they will continue to be selected even when another page is displayed.

Fixed issues

DataCapture

#8623, #9325 The selection lists in query and discrepancies reports were not always sorted and years were displayed in an unnecessarily short form.

The selection lists in reports are now sorted alphanumerically or by calendar date. Dates are now displayed with the complete year. The list of possible discrepancy statuses is sorted according to the order of assignment. The current method of sorting is indicated via an upwards or downwards pointing triangle next to the sorting criterion.

#9409 The entries in the query report couldn't be sorted by form and item.

This issue has been fixed. The entries can now be sorted ascending or descending in alphabetical order by form name and listed item label.

#9411 In a query report only the item label was shown for items. If the item label was not set, no label was shown at all.

This issue has been fixed. In a query report now the question label will be shown, if the item label has not been set (like in the discrepancy report).

#9412 In the discrepancy and query report the visit respectively the description of the adverse event or the casenode form family is displayed in a column. The display of adverse events was not consistent in both reports.

Both reports now display adverse events like in the query report. The column in the query report was renamed from "visit" to "event". The entries in the column can now be sorted ascending or descending in alphabetical order.

Fixed issues from 5.1.0

#9337 The secuTrial® version number was missing on the error pages and in the error message which is sent from the error page.

This issue has been fixed. The version number is now listed in the emails in the last row below the StackTrace.

FormBuilder

#9217 In some cases it was not possible to perform the setup single form export. An error message was displayed stating that more than the selected number of forms were contained in the form compilation. The error occurred if a form field from a subform contained in a form was referenced in a value development report and the subform was used in other main forms.

This issue has been fixed.

#9318 When generating the CRFs for a paper print out, only the patient forms were included and not the centre forms.

This issue has been fixed.

#9341 If an item from another visit form was used in a rule condition in a visit form and a specific visit was selected as a comparison source, only the visits from the rule form were offered and not the visits from the comparison form.

This issue has been fixed.

#9358 If a message is defined in a casenode or AE form as a following action or rule message, it is also possible to add questions from visit forms as the message content.

For visit forms, the options "current visit" and "previous visit" are available for relative visits. This had not been set up when triggering a message from a casenode (or AE form).

The message form is now also taken into account: if this is not a visit form, only "first" and "last" visit are offered.

#9362 In project messages that are defined for a form-based trigger such as "Query created", there is also a configuration option for the form URL to be sent as well. If the trigger was changed "Patient created" for such a message, an error (exception) occurred when creating a patient because this message could not be compiled. The patient was nevertheless successfully created.

This issue has been fixed. Any incorrectly configured message templates should be corrected.

#9369 When trying to create a second condition for a hide rule in a subform, an error (exception) occurred if a comparison with a specific visit value was defined in the already created condition.

This issue has been fixed.

#9384 The rule condition of a "Take value from" rule could not be fully saved if the metadata value to be adopted was to be selected from a specific visit. Although it was possible to select and save without an error message, upon saving the selected visit was reset to "Please select".

This issue has been fixed. The required visits must be manually added to any incomplete definitions of rule conditions.

- #9386 When editing the visit plan, an initial number of visits must always be entered. The error message "Visit plan must contain at least 1 visit as an initial number." was misleading, as it is also possible to enter "0". Furthermore, only projects could only be released if at least one visit had been created in the project, even if there were no visit forms.

The error message has been corrected. Projects can now be released if either at least 1 visit is defined or the initial number of visits is set to "0" and at least 1 form has been defined in the project.

AdminTool

- #9377 If a general or form-based SDV right have been set for a role, no form editing can be set for this role. This restriction continued even if the entire SDV function was deactivated. The general, role-based SDV rights assignment was also still possible.

This issue has been fixed. When editing a role after the SDV function has been deactivated in the customer or project, all SDV rights in the role are automatically reset.

DataCapture

- #8372 It was not possible to save a randomisation form (with randomisation upon saving) if a score contained in the form was used as a stratification factor for the randomisation and the score had not been actively calculated before saving. The error message was displayed that the randomisation could not be performed due to the missing score value.

This issue has been fixed. When saving a randomisation form, all scores contained in the form are calculated before the randomisation. After randomisation, the score calculation is performed once again during the normal calculation of rules for saving forms.

- #8390 When editing the visit plan, an error (exception) could occur if, due to date changes in the modified plan, a visit was displayed as the first visit which had been defined in the project template for the interval calculation "previous visit".

This issue has been fixed. In this case the patient entry date is used for calculating the intervals.

- #8643, #9296 In rule conditions relating to values in the first visit, it can be additionally configured that the condition in the first visit should not itself be calculated. Hide rules with such conditions were not correctly analysed. This could result in elements being hidden in the first visit, different hiding behaviours between the editing and read view of the form, or error messages (e.g. for missing values) being generated for items that were hidden in the editing view.

This issue has been fixed.

Note: Hide rules without any rule conditions are always applied. Hide rules with conditions that are not analysed in the first visit are all not applied.

- #9265 Rule conditions in visit forms relating to casenode forms could not be correctly analysed. The analysis was always conducted as if no value had been entered.

This issue has been fixed.

- #9332 If the web service data export was used very intensively with lots of requests per session, an increased amount of memory was required and could cause an out of memory error.

The use of memory for the web service exports has been optimised.

- #9340 If a label was defined for an adverse event or image form from a radiobutton, pop-up or lookup item, the database value was displayed in the form overview of the patient instead of the label of the value selected in the respective form.

This issue has been fixed.

- #9355 The menu button for the report page was not displayed if the current participant was assigned to more than one project and all released reports were only released for selected roles.

This issue has been fixed.

#9357 The hide rule was not always correctly analysed if the source value of the rule condition from a lookup item was compared with a fixed text via the operator "contains".

This issue has been fixed.

#9360 The query or comment window opened from a form was not closed when the breadcrumb trail in the navigation bar was used to switch to the welcome page or centre form overview.

This issue has been fixed.

ExportSearchTool

#9282 In the SAS export format the data structure for the tables of subforms, comments, queries, SDV and MV was incorrectly exported if the duplication of metadata was not selected but the individual entries for the metadata were selected. The metadata columns were exported but were not included in the calculation of the LRECL.

This issue has been fixed. The metadata columns are only exported in the tables if the duplication of metadata has been selected.

#9289 When exporting a project with blinded randomisation, possible unblinding and repetition of metadata, in some tables the data of non-randomised patients was not correctly exported, as in these datasets the empty column value was missing for the (not completed) randomisation item.

This issue has been fixed.

#9387 For radiobutton items an own label can be given for the reset value "not applicable" (=NULL). This label was only exported for CSV-exports, if the option "Store reference values in same table" was checked. The reset label was neither exported in the extra codelist table for CSV nor included in the codelists of the SAS export.

This issue has been fixed. The reset label is now included in the codelists of the CSV export and SAS export. When exporting data of radiobutton items in SAS values which haven't been set (=NULL) will be exported with a single dot.

Issues fixed from 5.0.1

#9186, #9361 In very rare cases, it could occur that a query in a form A was created for an item from another form B. The error happened if the query window was not closed when switching between the forms via the breadcrumb trail. The created query was not displayed in either of the two forms and the query report could not longer be displayed (exception). The link between query, item and form had to be directly corrected in the database.

This issue has been fixed. The query window is now always automatically closed when switching between forms.

Issues fixed from 5.0.0

DataCapture

#9297 When a "Hide rule" was created for an item in a subform which was based on another item from the previous visit in the main form, the entries were hidden but the heading was still displayed. (If "current visit" was entered as the source, the rule was correctly calculated.)

This issue has been fixed.

Issues fixed during development

The following issues were found during development and fixed:

#8513, #8624, #9268, #9271, #9275, #9276, #9277, #9278, #9279, #9288, #9290, #9325, #9326, #9327, #9350, #9351, #9352, #9353, #9376

Deployment

Database

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