secuTrial® 5.0.2.12 – Version history

Based on Version 5.0.1.21

Introduction

This version contains a number of additional import functions, two new web services for automated data export and the possibility to refer to metadata in rule conditions (status information during form entry):

New Functions

1. Import

Merging columns sT5.0-6.1, #8252

Data that is separately listed within an import file can now be merged during import and can be imported as a single value into a single item. For example, this function can be used to import separately listed time and date values into a single time and date item. It would also be possible to import two text values into a single, larger text field or the separately listed digits before and after the decimal point of a number into a single number item.

To enable this function, one or more data preprocessing steps must be defined in the import format or in the import configuration. The first step is to specify which external variables (=column headings) contain the two separate values in the import file and under which new external name this data should then be processed. Under format (maximum 100 characters), it must then be specified how value {1} and value {2} are to be linked together: you can specify the order, character before and after the new value or a character between the two values (see Fig. 1, bracket 1).

In the import format, you can then define the mapping with which the new merged import value is assigned to an item.

The preprocessing specification in an import configuration is used for multi-mass imports. The specification in an import format is used for a mass import into a single form or a single form import.

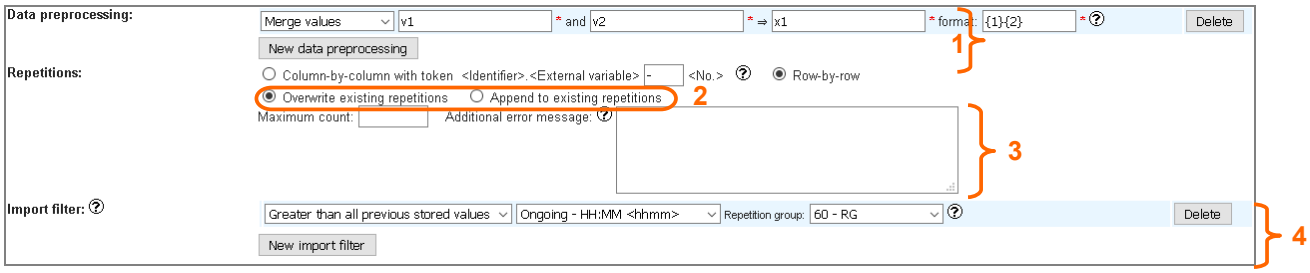

Fig. 1: Specification options for data preprocessing (bracket 1, see above), the handling of repetitions (circle 2), the maximum number of repetitions (bracket 3) and the import filter (bracket 4) in an import format.

Extended configuration of the CSV parser

Treatment of format errors #8635

When using a CSV parser, a table-type CSV file is expected containing the external keys as column headings in the first row and the values belonging to the keys in the rows underneath. The number of columns should correspond in all of the rows.

In previous versions, all files in which the number of columns was not the same in all rows were rejected with errors and the import could not be performed.

It is now possible to define in every CSV parser whether such format errors should be treated as an "error" just as previously or only as a "warning" (see Fig. 2, highlight 1). In the case of a "warning", after uploading the CSV file only a warning will be displayed, the import can still be performed. The first row containing the column headings will be used as the basis for the table format: if there are too few columns in the data rows, these will be filled with empty values (NULL), excess columns will be ignored.

Trimming values #8634

In previous versions, all data in CSV files that was encompassed by the specified delimiter (e.g. quotation marks) or – if there were no delimiters – delimited by separators was interpreted as data without further processing. This also applied for leading or trailing blanks.

It is now possible to configure whether the data should be trimmed when parsing the CSV file before it is analysed (see Fig. 2, highlight 2). During import, all leading or trailing blanks or other blank symbols (e.g. tabs) are removed. Blanks (and empty spaces) within texts will be retained. Data that only contains blanks or white spaces will be reduced to an empty text (this is interpreted as NULL during import).

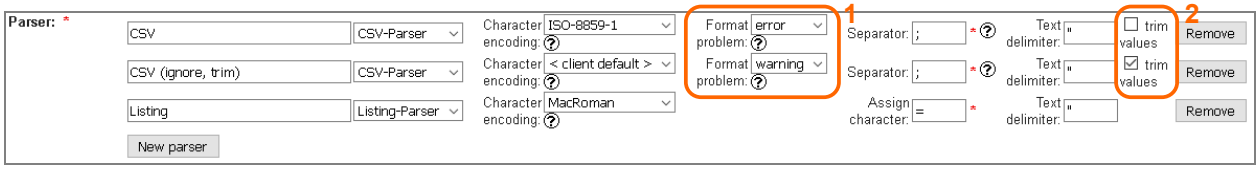

Fig. 2: Definition of import parsers with the configuration for the treatment of format errors (highlight 1) and trimming values (highlight 2).

Appending to or overwriting repetitions

When defining the treatment of repetitions in import formats, you can specify whether all repetitions for a form should be overwritten in the same way as before or whether all imported repetitions should be appended to already existing repetitions (see Fig. 1, highlight 2).

Filtering repetition datasets sT5.0-6.2, #8325

In the case of multiple imports of the same file, you can prevent the data from being imported all over again by defining import filters in import formats. The filter discards all repetitions within a dataset that do not correspond with the defined filter criterion.

One or more items from the contained subforms can be selected as the filter criterion. The respective repetition group of the main form (for which the import format is defined) must also be specified (Fig. 1, highlight 4).

When performing the import, only the repetitions in which the entry in the import file is greater than the previously saved entries in all of the patient's datasets will be imported.

For example, in the case of measurement values with measurement times in a repetition, this can be used to ensure that only new measurements are imported.

Maximum number of repetitions during import sT5.0-6.3, #8324

If there is a very large number of repetitions (approx. more than 1,000) within a dataset, this can result in memory problems in secuTrial® DataCapture. It is not possible to state an exact limit for the number of processable repetitions because this depends on numerous factors, e.g. the configuration of the application and the number of values within the repetitions.

After testing the respective projects to determine the applicable limit, a maximum number of permitted repetitions can then be specified for each import. When this limit is reached, the import will be stopped during the analysis and an error message will be displayed. The error message contains a system element (in which the number of contained repetitions is listed, first sentence in Fig. 3) and a configurable text (max. 1,000 characters) (see Fig. 1, highlight 3, second sentence in Fig. 3).

This configuration can be specified in the import configuration and in the import format. For a multi-mass import, the settings from the configuration are used. For a mass import and single form import, the settings from the import format are used.

To calculate the number of repetitions in the import file, all repetitions in a dataset are added together, regardless whether they are contained in a single repetition group or multiple repetition groups. Repetitions that have previously been excluded by a filter (see below) will not be taken into account.

Fig. 3: Error message upon exceeding the maximum permitted number of repetitions during a single form import in DataCapture.

Extended date formats #8636

When entering import mappings for date and time items, in addition to the selection list with preset data formats displayed according to item type, it is now also possible to freely enter formats for the imported value. To do this, select the option "other format" in order to enter the expected date or time format in a text field as required. As date formats can also contain the names of months, if a free text entry is selected, it is also possible to select the language with which the imported values are to be analysed (see Fig. 4).

The date formats can be specified with the following symbols (Java SimpleDateFormat, note the use of capitals and lower case letters!). Each date/time element displayed in the item type must be entered in the new format.

- yy, yyyy

  = year. Full year dates are entered as "yyyy". If two-digit year dates "yy" are entered, these are interpreted within the time frame of 20 years in the future and 80 years in the past calculated from

the current date. For example, if an import is performed in 2016, the year date "28" will be interpreted as "2028", but "66" will be interpreted as "1966".

- M, MM, MMM, MMMM

  = month. For a two-digit entry, leading zeros might be expected. For the three-digit entry "MMM" an abbreviation of the month name might be expected, for the four-digit entry "MMMM" the complete month name. As month names are language specific, it is necessary to specify the language which is to be used during the import.

- d, dd

  = day in month. For a two-digit entry, leading zeros might be expected.

- H, HH

  = hour (0-23). For a two-digit entry, leading zeros might be expected.

- m, mm

  = minute (0-59). For a two-digit entry, leading zeros might be expected.

- s, ss

  = seconds (0-59). For a two-digit entry, leading zeros might be expected.

If partial entries might be missing in the file which is to be imported, either all separators must exist for the missing entries or the missing elements must be at the end of the date text. If there are no separators in the date, all missing elements must be replaced with placeholders.

The above information can also be found in the online help text, which can be opened by clicking on the question mark next to "Date format" in the heading of the import mapping properties. It is also possible to test date formats and values against each other there (see Fig. 5).

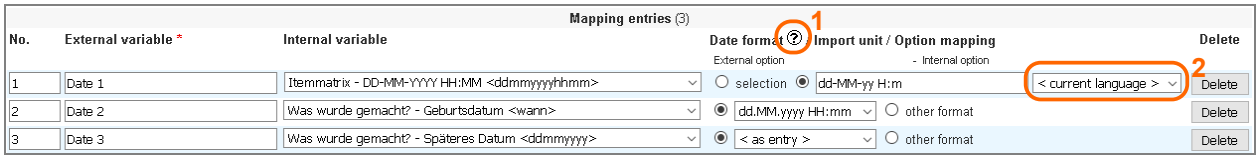

Fig. 4: Possible entries of date formats when mapping date items: free entry with language selection (first row, highlight 2), selection from a preset list (second row), <as entry> (third row). Click on the icon in the title row (highlight 1) to open a help text explaining the formats (see below).

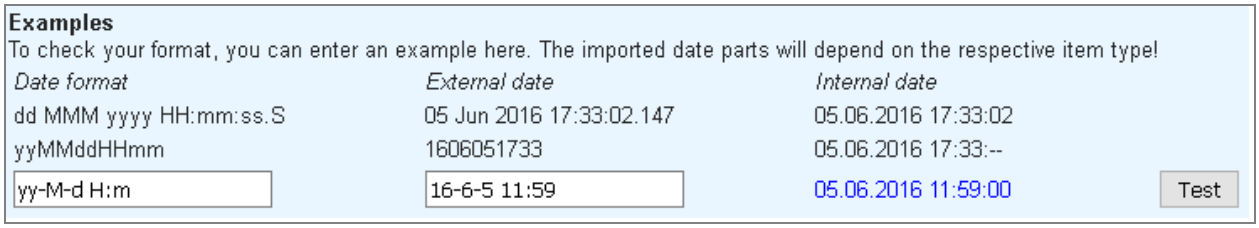

Fig. 5: Excerpt from the help window for the date formats with examples and test option.

Creating centres sT5.0-5.3, #8253

During an import, any unknown centres contained in the imported data will be newly created if the participant is either assigned to the import project as a project participant or if the participant's role has been specified for future centres for this project.

The centre will then be created for the import project and all participants with roles for future centres within this project will be assigned to the centre with these roles.

If no future role can be found, the centre will not be created and the dataset import will be rejected with an error message.

If a centre with a role assignment was successfully created, the next import steps for this dataset will be performed with this role.

2. Web services

As is the case with the existing import web service, the export web services are implemented as SOAP interfaces.

When importing and exporting any type of data, the role rights of the currently logged in participant are checked. Via the web services, it is only possible to export or import the data that is normally accessible when a participant is logged in to DataCapture.

Password expiry #8578

Like the import service, the new export web services implement the methods `authenticate` and `terminate`. In order to use the web services, participants created in secuTrial® must authenticate themselves with their user name and password. However, as these services are particularly intended for automatic exchange of data, it is recommended that separate participants are created for this purpose. The otherwise usual expiry period for the validity of passwords can then be deactivated for these participants.

This configuration also applies for the normal participant login for the secuTrial® tools.

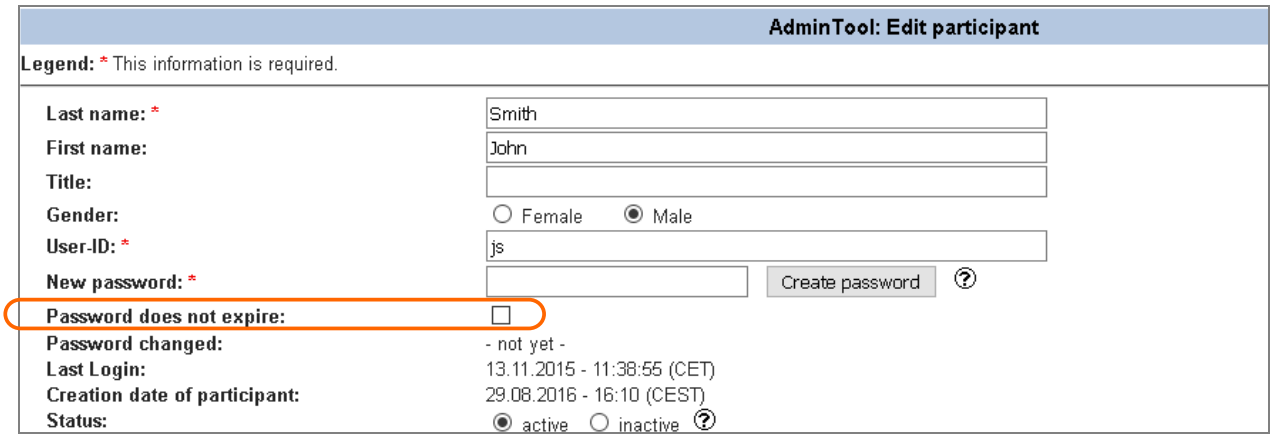

Fig. 6: Option for deactivating password expiry (highlighted) on the participant editing page in the AdminTool.

Note: Due to the introduction of this new configuration, the procedure for logging in to the import web services has also changed: it is no longer possible to log in to a service if the password is valid but has expired and the new validity option has not been selected.

Session timeout #8477

Until now the session timeout for all web services was set to 1 minute. This time can now be configured using the new start parameter "`-DSRTWebServiceSessionTimeout`" in the WOMonitor for all web services of the respective tool.

The timeout is entered in seconds (also see section: Deployment - WOMonitor).

Export project data sT5.0-5.2, #8540, #8373

This export service generates information about the centres, patients and all structure data and metadata for an individual patient in a project. For individual patients, this information comprises the created visits, adverse events and images. This information corresponds to the different views of the patient's form overview including all status information. In addition, the editing history of the forms can be exported using this web service.

This information can then be used to export individual forms with the saved form data.

In order to use this web service, it must be activated for the respective DataCapture by setting the start parameter "`-DSRTProjectDataService=true`" in the WOMonitor (also see section: Deployment - WOMonitor).

The WSDL of this web service can be called up via the following URL:

[DataCapture-URL]/ws/ProjectDataService?wsdl

This service implements the following operations (exact description below):

- authenticate
- terminate
- projectData
- centreData
- patientData
- visitData
- adverseEventData
- casenodeData
- imageData
- formData

All operations return a result object comprising:

- statusCode (1=successful, 0=failed)
- errorCode (0=no error, for codes see: Error codes)
- message

The status code indicates the success or failure of the operation. Status code=1 shows that the operation was successful; upon authentication the session ID is returned as the event object in the "message". If an operation fails, the problem is classified by the error code and the "message" will contain a description of the error.

If it is successful, in addition to this basic information the data export operations will contain data objects or lists of data objects containing the respectively required data.

Description of individual operations

"authenticate"

Login to the secuTrial® server with entry of a valid participant in the customer area; generates a session with which additional operations can be performed.

Specifications in the request	
customerId	DB customer abbreviation (unique within a secuTrial® installation)
username	User name (=login) of the participant (unique within a customer)
password	Participant's password
Specifications in the response	
message	ID of the created session with successful authentication, otherwise error message

"terminate"

Logout from the secuTrial® server and termination of the session

Specifications in the request	
sessionId	ID of the session which is to be terminated

"projectData"

List of all centres created in the project.

Specifications in the request	
sessionId	ID of the current session
project	Schema name of the project (unique within a secuTrial® installation)
Specifications in the response	
project	Schema name of the project (unique within a secuTrial® installation)
centres	List of centres in the project (as **"CentreBean"**)

"centreData"

List of all patients contained in a centre

Specifications in the request	
sessionId	ID of the current session
project	Schema name of the project (unique within a secuTrial® installation)
centre	Centre name (unique within a customer)
Specifications in the response	
project	Schema name of the project (unique within a secuTrial® installation)
centre	Centre name (unique within a customer)
patients	List of all patients within the centre (as **"PatientBean"**)

"patientData"

List of all events created for a patient and their status: visits, adverse events, casenode, image forms

Specifications in the request	
sessionId	ID of the current session
project	Schema name of the project (unique within a secuTrial® installation)
centre	Centre name (unique within a customer) Entry is optional. If no name is entered for a centre, the patient's home centre will be used.
patient	Specification of a patient (as **"PatientBean"**)
Specifications in the response	
project	Schema name of the project (unique within a secuTrial® installation)
centre	Centre name (unique within a customer)
patient	Specification of a patient (as **"PatientBean"**)
adverseEvents	List of all adverse event examinations (as **FollowupStatusBean**)
image	Summary of the status of all image forms (as **FormsetStatusBean**)
casenodes	List of all casenode form families (as **FormsetStatusBean**)
visits	List of all visits (as **VisitStatusBean**)

"visitData"

List of all forms within a visit with their respective form status.

Specifications in the request	
sessionId	ID of the current session
project	Schema name of the project (unique within a secuTrial® installation)
centre	Centre name (unique within a customer) Entry is optional. If no name is entered for a centre, the patient's home centre will be used.
patient	Specification of a patient (as **"PatientBean"**)
visit	Specification of the visit (as **VisitBean**)
Specifications in the response	
project	Schema name of the project (unique within a secuTrial® installation)
centre	Centre name (unique within a customer)
patient	Specification of a patient (as **"PatientBean"**)
visit	Specification of the visit (as **VisitBean**)

forms	List of all forms (as **FormStatusBean**)

"adverseEventData"

List of all examinations for an adverse event with the summarised status of all forms in an examination

Specifications in the request	
sessionId	ID of the current session
project	Schema name of the project (unique within a secuTrial® installation)
centre	Centre name (unique within a customer) Entry is optional. If no name is entered for a centre, the patient's home centre will be used.
patient	Specification of a patient (as **"PatientBean"**)
ae	Specification of the AE (as **AdverseEventBean**)
Specifications in the response	
project	Schema name of the project (unique within a secuTrial® installation)
centre	Centre name (unique within a customer)
patient	Specification of a patient (as **"PatientBean"**)
ae	Specification of the AE (as **AdverseEventBean**)
forms	List of all forms for an AE examination (as **FormStatusBean**)

"casenodeData"

List of all possible casenode forms with their respective form status

Specifications in the request	
sessionId	ID of the current session
project	Schema name of the project (unique within a secuTrial® installation)
centre	Centre name (unique within a customer) Entry is optional. If no name is entered for a centre, the patient's home centre will be used.
patient	Specification of a patient (as **"PatientBean"**)
Specifications in the response	
project	Schema name of the project (unique within a secuTrial® installation)
centre	Centre name (unique within a customer)
patient	Specification of a patient (as **"PatientBean"**)
sets	List of all form families (as **FormsetDetailedStatusBean)**

"imageData"

List of all created image forms with their respective form status

Specifications in the request	
sessionId	ID of the current session
project	Schema name of the project (unique within a secuTrial® installation)
centre	Centre name (unique within a customer) Entry is optional. If no name is entered for a centre, the patient's home centre will be used.
patient	Specification of a patient (as **"PatientBean"**)
Specifications in the response	
project	Schema name of the project (unique within a secuTrial® installation)
centre	Centre name (unique within a customer)

patient	Specification of a patient (as **"PatientBean"**)
label	Name of the form family
forms	List of forms (as **FormStatusBean**)

"formData"

Lists the form status of an individual form and the editing history.

Specifications in the request	
sessionId	ID of the current session
dataRecord	Specification of the form (as **FormDataRecordBean**)
Specifications in the response	
dataRecord	Specification of the form (as **FormDataRecordBean**)
status	Status of the form (as **DocumentStatusBean**)
history	List of form edits (as **DocumentHistoryBean**)

Data objects

The different return data objects contain the following specifications:

"CentreBean"

name	Centre name (unique within a customer area)

"PatientBean"

psd	The patient's Pat-ID (unique within a customer area, only set if the participant role is permitted to see this pseudonym)
aid	The patient's Add-ID (it can be zero, unique within a customer area, only set if the participant role is permitted to see this pseudonym)
labid	The patient's Lab-ID (unique within a customer area, only set if the participant role is permitted to see this pseudonym)
entrydate	Entry date of the patient in the project in the format "`dd.MM.yyyy`"

"VisitBean"

label	Name of the patient visits as displayed in DataCapture (depending on type with integrated numbering, see below.)
date	scheduled visit date in the format "`dd.MM.yyyy`"
nr	The numbering corresponds to the patient's visit plan (scheduled visits are consecutively numbered in their order of creation, unscheduled visits are listed by type in their order of creation)

"VisitStatusBean" (extended VisitBean)

status	Summarised status of all forms for the visit (as **DocumentStatusBean**)

"AdverseEventBean"

aenr	Number of the adverse event (consecutive numbering within the patient in the order of creation)
aedate	Date of the adverse event in the format "`dd.MM.yyyy-HH:mm`"
issae	Distinction between AE / SAE (boolean, true=SAE)
fudate	Date of the examination in the format "`dd.MM.yyyy-HH:mm`"

"FollowupStatusBean" (extended AdverseEventBean)

status	Summarised status of all forms for the examination (as **DocumentStatusBean**)

"FormsetStatusBean"

label	Name of the form family
status	Summarised status of all forms from the form family displayed in the patient (as **DocumentStatusBean**)

"FormsetDetailedStatusBean"

label	Name of the form family
forms	List of forms (as **FormStatusBean**)

"FormStatusBean"

form	Database table name of the form (unique within a project)
status	Status of the form (as **DocumentStatusBean**)

"DocumentStatusBean"

completion	Completion status of the form(s) according to the rule structure: 0 = not saved / empty, 2 = partially completed, 4 = fully completed
review	Combined review status (bit mask): -4= not savable (all), -1 = not saved (all), 0 = not saved / without, 32 = review A (all), 64 = review B (all), 128 = manual freeze (all), 512 = review A (partial), 1024 = review B (partial), 256 = rule freeze (all)
query	Query status: 0 = not saved / without or withdrawn query, 1 = with open query, 2 = with answered query, 4 = with closed query
comment	Comment status: 0 = not saved / without, 1 = with
sdv	SDV status: 0 = not saved, 1 = not executed, 2 = not necessary, 16 = in editing, 32 = verified, 64 = verified with problems
error	Error status: 0 = not saved / without, 8 = with errors
warning	Warning status: 0 = not saved / without, 16 = with warnings
dec	DEC status: 0 = not saved / without, 32 = set with DEC
patient	Patient status: 0 = active, -5 = deceased, -2 = frozen
storable forms	Number of forms which can be saved (with database table)
documents	Number of saved documents

"DocumentHistoryBean"

date	Editing date in the format "`dd.MM.yyyy-HH:mm:ss`"
user	Full name of the editing participant in the format "title, first name, surname" or set text "Patient" if edited by the patient (as part of PSD)
event	Written description of the editing (in the language used by the user interface at the time)
eventType	Coded information about the editing (corresponds with the "sigstatus"

	entry in the ExportSearchTool exports): 1 = data edited 2 = review A 3 = review B 4 = comment 5 = query asked 6 = query answered 7 = data freeze 8 = data unfreeze 9 = sdv 10 = revoke review A 11 = query resolved 12 = data entry complete 13 = modify data 14 = manual freeze 15 = data import 16 = revoke entry complete 17 = Query withdrawn 19 = DDE entry 20 = DDE entry completed 21 = DDE entry reopened 22 = DDE comparison finished 23 = DDE entry corrected 24 = revalidate
version	Project version with which the editing was performed (assigned label in the productive area, project version time stamp in the setup area)

Form data exports sT5.0-5.1, #8254, #8477

This export service can be used as an interface to the automatic export of individual patient form data. The form is selected by specifying the project, patient, event (visit or adverse event) and the required form.

In order to be able to use this web service, it must be activated for the respective DataCapture by setting the start parameter "`-DSRTFormDataExportService=true`" in the WOMonitor (see also section: Deployment - WOMonitor).

The WSDL of this web service can be called up via the following URL:

[DataCapture-URL]/ws/FormDataExportService?wsdl

This service implements the following operations (exact description below):

- authenticate
- terminate
- export

All operations return a result object comprising:

- statusCode (1=successful, 0=failed)
- errorCode (0=no errors)
- message

The status code indicates the success or failure of the operation. Status code=1 shows that the operation was successful; upon authentication the session ID is returned as the event object in the "message". If an operation fails, the problem is classified by the error code and the "message" will contain a description of the error.

If it is successful, in addition to this basic information the data export operations will contain data objects or lists of data objects containing the respectively required data.

Description of individual operations

The operations "authenticate" and "terminate" are the same as the ones described in the project data service.

"export"

Returns the data (content) of a form. The form is identified via the form table name or the identifier of an import format. Depending on the form type, the visit or adverse event must be defined with a corresponding bean. The sent bean filled with the item data of the form is then returned as the result.

If the form was identified via an import format, the import format is also used for returning the values and these are recoded if necessary.

Specifications in the request	
sessionId	ID of the current session
dataRecord	Specification of the form (as **FormDataRecordBean**)
Specifications in the response	
documentid	Document ID of the form
dataRecord	Specification of the form (as **FormDataRecordBean**)

Data objects

"FormDataRecordBean"

project	Schema name of the project (unique within a secuTrial® installation)
centre	Centre name (unique within a customer) Entry is optional. If no name is entered for a centre, the patient's home centre will be used.
patient	Specification of a patient (as **"PatientBean"**)
visit	optional: Specification of the visit (as **VisitBean**)
ae	optional: Specification of the adverse event examination (as **AdverseEventBean**)
form	Specification of the form (as table name or import format identifiers)
item	optional: List of form data (as **FormDataItemBean**)

"FormDataItemBean"

key	Column name of the item; items within a repetition are extended with the hash value of the repetition group
value	Saved item value; not entered values (NULL) are returned exported as empty text. If the was identified via an import format, all item values with a defined value mapping will be re-coded.
repindex	Position of the repetition (starting at 0); values from main forms are set to "-1".

Error codes

The following numbers are displayed as error type codes for the various services in the *errorCode* field. Most of the codes are only used by one service, but a few of the codes may be used by multiple services.

All services		
0	ERRORCODE_NO_ERROR	No error
1	ERRORCODE_NOT_AUTHENTICATED	Login failed
2	ERRORCODE_PASSWORD_EXPIRED	Password has expired
ProjectDataService		
201	ERRORCODE_OPERATION_ERROR	Error executing the operation
202	ERRORCODE_ACCESS_ERROR	Not authorised
FormDataService		
301	ERRORCODE_INVALID_PATIENT	Invalid patient

302	ERRORCODE_FORMDATA_ERROR	Invalid form
FormTransmissionService		
100	ERRORCODE_MISSING_CONFIG	Missing import configuration (or format)
101	ERRORCODE_MISSING_DATA	No data entered
102	ERRORCODE_MISSING_PROJECT	No project specified
103	ERRORCODE_INVALID_PROJECT	Invalid project specified
1002	ANALYSIS_WARN	The import contains valid and invalid data (warning)
1003	IMPORTED_WARN	The import contains warnings (warning)
1004	IMPORTED_WITH_ERRORS	Only some of the data was able to be imported. (warning)
1005	IMPORTED_WITH_RULE_VIOLATION	Imported with rule violations (warning)
1006	DUPLICATE_PATIENT_IDENTIFIERS_IN_IMPORT	A patient is duplicated in the import (warning)
1007	DUPLICATE_IIF_IDENTIFIERS_IN_IMPORT	An import identifier is duplicated in the import (warning)
1008	UNKNOWN_CENTRE_IDENTIFIER	New centre (warning)
1009	IMPORTED_ERROR	Import error
1010	PARSE_ERROR	Parse error
1011	ANALYSIS_ERROR	Analysis error: no valid datasets
1012	DATA_VALUE_PARSE_ERROR	Invalid (visit / AE / patients) date
1013	INVALID_PROJECT_IDENTIFIER	Invalid project
1014	INVALID_CENTRE_IDENTIFIER	Invalid centre
1015	INVALID_FORM_IDENTIFIER	Invalid form
1016	INVALID_VISIT_DATA	Invalid visit data
1017	INVALID_AE_DATA	Invalid adverse event data
1018	PATIENT_NOT_FOUND	Patient not found
1019	PATIENT_WITH_IMPORTIDMAPPING_NOT_FOUND	Patient was not found via the import form field
1020	PATIENT_WITH_IMPORTIDMAPPING_FOUND_MORE_THAN_ONE	Multiple patients were found via the import form field
1021	PATIENT_PSD_MISMATCH	Pat-ID does not match the patient
1022	PATIENT_PID_MISMATCH	Patient ID does not match the patient
1023	PATIENT_AID_MISMATCH	Add-ID does not match the patient
1024	PATIENT_LABID_MISMATCH	Lab-ID does not match the patient
1025	PATIENT_ID_MISMATCH	The entered Pat-ID does not match the patient
1026	PATIENT_IDENTIFIER_MISSING	The entered pseudonyms do not match
1027	PATIENT_PID_MISSING	Pat-ID is missing
1028	PATIENT_AID_MISSING	Add-ID is missing
1029	PATIENT_LABID_MISSING	Lab-ID is missing
1030	PATIENT_PID_COLUMN_MISSING	Pat-ID column is missing
1031	PATIENT_AID_COLUMN_MISSING	Add-ID column is missing
1032	PATIENT_LABID_COLUMN_MISSING	Lab-ID column is missing
1033	PATIENT_IDMAPPING_COLUMN_MISSING	The column for identifying the patient via the form field is missing
1034	PATIENT_IDMAPPING_IMPORT_COLUMN_COLLISION	The import contains additional data for the form field which is being used to identify the patient
1035	PATIENT_STATUS_INACTIVE	Inactive patient

1036	PATIENT_STATUS_DEAD	The patient is deceased
1037	NO_PATIENT_EDIT_RIGHT	No editing rights for this patient
1038	PATIENT_NOT_IN_PROJECT	The patient is not in the project
1039	PATIENT_DIFFERENT_CENTRE	The patient is assigned to a different centre
1040	PATIENT_WRONG_CENTRE	The patient is assigned to a different centre
1041	INVALID_ENTRYDATE	Invalid entry date
1042	NO_VISIT	No visits were found
1043	NO_VISIT_FOR_VALUE	No visits were found
1044	VISIT_NOT_EDITABLE_FOR_CENTRE	Visits cannot be edited for this centre
1045	VISIT_VALUE_AMBIGUOUS	Visit is not clearly identified
1046	VISIT_DATA_AMBIGUOUS	Visit is ambiguous (form in multiple visits).
1047	VISITS_COLUMN_MISSING	The column for visits is missing
1048	VISIT_VALUE_MISSING	The entry for the visit is missing
1049	VISIT_DATE_MISSING	The visit date is missing
1050	NO_CASENODE	There is no project entry for patients
1051	NO_AE	No adverse event was found
1052	NO_FOLLOWUP	No AE follow-up examination was found
1053	AE_DATE_MISSING	The adverse event date is missing
1054	AE_NR_MISMATCH	The adverse event data is invalid (date and number do not match)
1055	FU_DATE_MISSING	The AE follow-up examination date is missing
1056	FU_DATE_AMBIGUOUS	AE follow-up examination date is ambiguous
1057	DOCUMENT_IS_READONLY	The document can only be read
1058	FORM_IS_DDE	The form is a DDE form
1059	PRE_CONDITIONS_FAILED	The form conditions have not been fulfilled
1060	COULDNT_LOCK_DOCUMENT	Unable to freeze form for editing
1061	GENERAL_EXCEPTION	General error
1062	FORM_NOT_IN_VISIT	The form does not exist in the visit
1063	FORM_UNUSED	Form unused
1064	FORM_NO_DATA	The form does not contain any data
1065	DATARECORD_NOT_IMPORTED	The dataset was not imported
1066	CREATION_NOT_POSSIBLE	Not possible to create
1067	PROJECT_CLOSED_FOR_EDITING	Data entry has been closed in the project
1068	KEY_VALUE_MISMATCH	Invalid data values

Web services Java client #8682

To make it easier to use the different DataCapture web services, a basic implementation for Java clients has now been provided. This can be used to communicate with the secuTrial® web service operations and convert the return values to Java Bean objects.

The stub implementation of the clients is provided as a Zip file. This contains:

- Readme.md
  Text file with instructions for using the clients
- secutrialwsclients.jar
  Java implementation of the secuTrial® web service clients
- lib
  All of the Java libraries used

- src
  Source code of the client implementations
- doc
  API Javadoc

3. Messages: Form as a PDF attachment in emails sT5.0-7.0, #8321

In messages that have been defined as form or rule messages, all of the associated forms can now also be sent as a PDF attachment with the message. This is specified in the message definition (see Fig. 7).

When the message is triggered in DataCapture, the currently saved form is generated as a PDF and attached to the message if it is being sent as an email. This does not apply to internal messages.

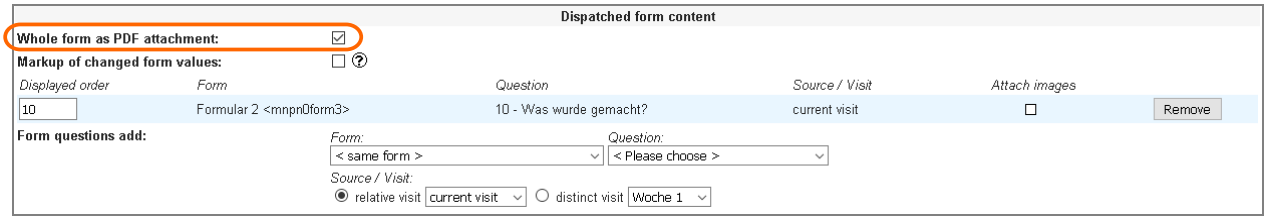

Fig. 7: Definition of a form message with PDF attachment specified (see highlight).

4. Printed validation report sT5.1-4, #8255

Similar to a query report, it is possible to create a separate printout of the validation report. In this printout, all notifications and any queries or comments for every item with error messages are summarised on one page per item. On this page there are free text fields for entering value changes, justifications and a signature. All pages relating to a patient are combined in a PDF file and all of the PDF files are bundled together for downloading in a Zip file with sub-folders for each centre.

Print view

The pages of the printout are grouped into the following sections:

A) Title row
The name of the project, the date of the printout, the centre and the patient are listed here. This title row is repeated at the top of every printed page if more than one page is required to display the information about an individual item due to the amount of text, error messages, queries or comments.

B) Information
This section contains the entered printout title (1) and the information text (2).

C) Item
The respective item is listed with context information (3, configurable scope) and all of the error messages, queries and comments. The display of queries and comments can be selected for each printout. The saved value in the form and a free text field for entering possible value changes (4) can also be displayed (configuration per report).

Each of the during form save generated validation messages will be displayed as a numbered paragraph, according to an entry in the validation report. Each paragraph can consist on multiple lines:

1. The error message as specified in the rule condition (or rule).
2. The definition of the violated rule condition with the values as compared during the time of form save (value source is specified by table name + column name and visit reference). This line is optional, it is only displayed if the option "rule" has been selection in the report or print-out selection page.
3. The currently stored compared values, if there are referenced from another form or visit, the value source is also listed (specified as form name + item text and visit reference). If the current item value or a fixed value has been used for comparison, this will not be listed.

The listing of all query and comment entries and of the currently stored compared values distinguish the online display of the validation report from the print-out.

D) Answer
In this section a reason can be entered for the current value or a value change. The information text can be configured (5).

E) Signature
In this section a signature must be entered for the explanations and/or value changes. The sentence requesting that the name is entered in legible block letters is optional (6). The label below the signature line (7) can also be configured.

The printout can be launched directly from the open report or from the report overview. In the latter case, a page will open to pre-filter the printout. The printout is always generated in the background and is then offered as a Zip file for downloading.

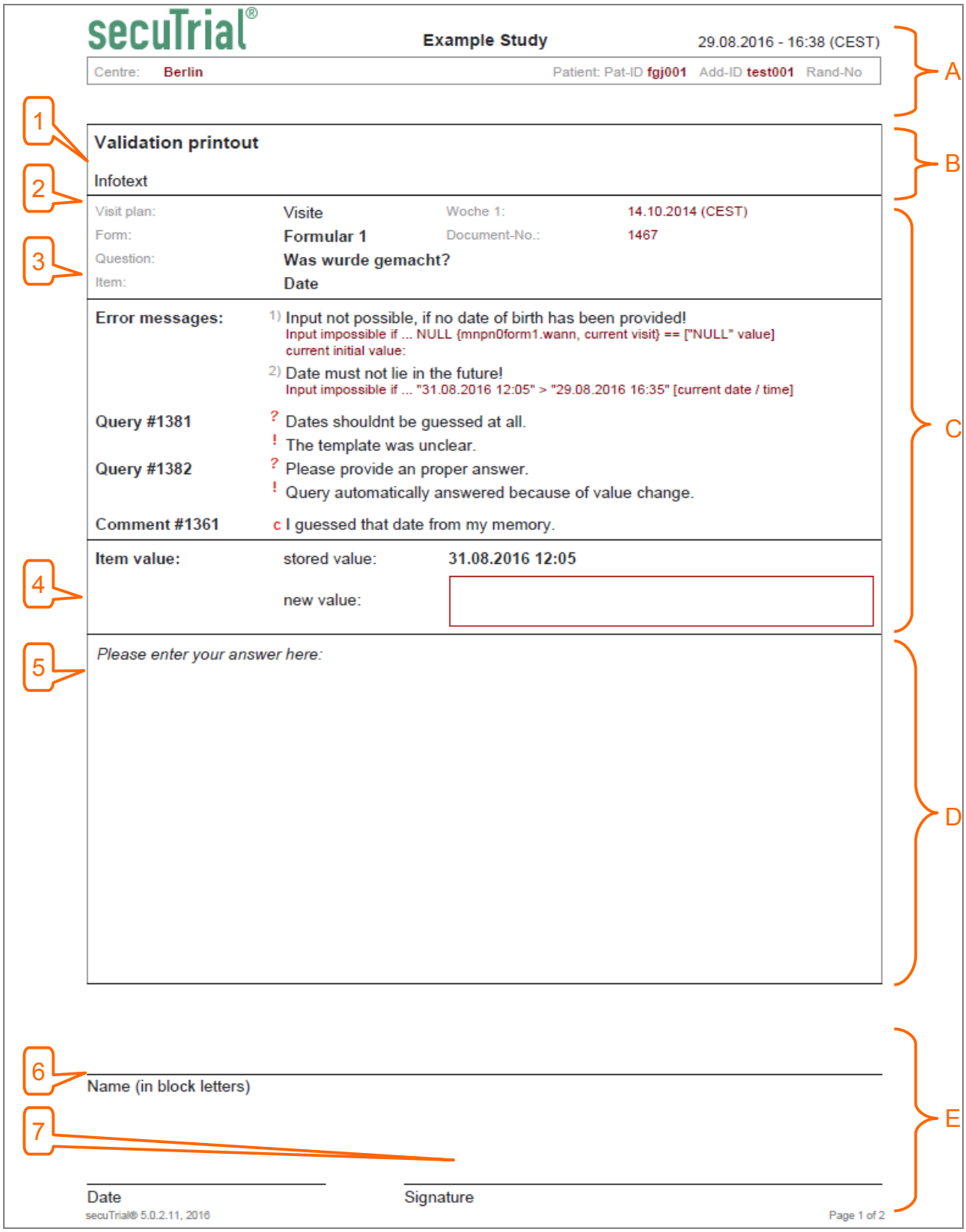

Fig. 8: Example page of the validation printout with 2 error messages, 1 query and 1 comment.

Configuration in the FormBuilder

When selecting the "Print" option, the following sections can be specified (see Fig. 8 and Fig. 9):

1. Title
   This text (max. 200 characters) is used as the menu link and the header in the printout.

2. Information text on the print page (HTML)
   This text will be displayed below the title on the printout. It can be formatted with HTML (please ensure the validity of the format!).
3. Context information
   This determines the scope of the context information for the respective item. The option "all" will display the generally valid item text, question text, form name, document number and any visit or adverse event information for the individual patient's form. If "reduced" is selected, only the generally valid information will be displayed and not the individual information.
4. Item value
   The item value saved in the form will be displayed, including an additional free text field for entering a possible value change.
5. Instruction in the comment area
   This text (max. 200 characters) is displayed in the free text field for entering a reason. Unless otherwise specified, a default text will be displayed.
6. Separate section for signature
   If this option is selected, a line for entering a name in clearly legible form (block capitals) will be inserted above the signature line.
7. Alternative to the word "Signature"
   An alternative word to "Signature" can be entered here (max. 200 characters).

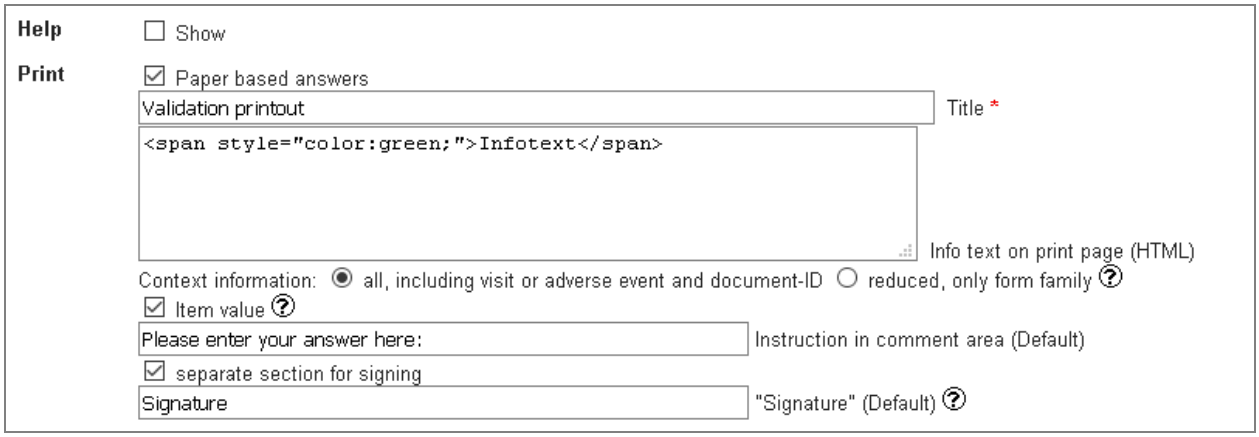

Fig. 9: Definition of the validation report printout for paper-based answers.

Report overview printout

If the printout has been configured, in the report overview the name of the printout title is displayed as an additional link behind the name of the validation report.

This link opens a small browser window for configuring the scope of the printout. The following options can be selected:

- Centre: all centres or a single centre selected from the participant's list of project centres
- If a centre is selected, Patient: all patients or a single patient selected from the list of patients for the selected centre
- Visit: all visits or a single visit selected from the list of project visit templates (if no patient has been selected) or from the list of visits for the selected patient
- Form: all forms or a single form selected from the list of forms for the current project
- If a single form is selected: all questions or a selected question from the form
- If a single question is selected: all items or a selected item from the list of items for the question
- Rule: The definition of the violated rule condition including the values during the time of save (the currenty stored compared values are always displayed if they were coming from another form or visit).
- Queries: include all queries for the selected items

– Comments: include all comments for the selected items

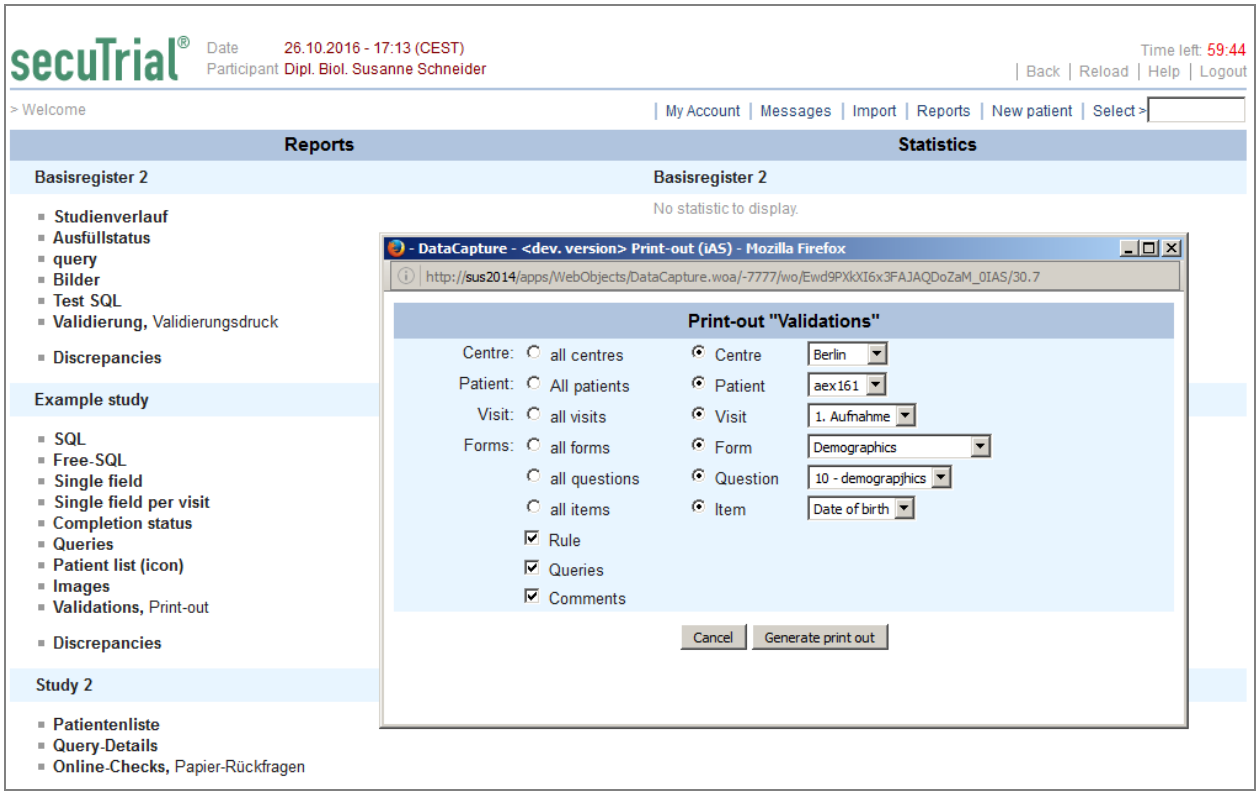

Fig. 10: Report overview with open selection window for printing out the validation report.

After selecting the required options, you can then generate the printout. During this process a progress bar will be displayed in the selection window. The generation of the printout can also be cancelled by clicking on the button in the progress window.

After the printout has been generated, a link for downloading it will then be displayed in the window. All of the PDF data is compressed into a Zip file for transfer.

Printout from an open report

A printout can also be generated from open validation report. In this case, all of the currently displayed validation notifications will be printed. There is no separate selection or filtering option. The inclusion of queries and comments depends on the query and comments status currently displayed in the report window (see below).

Click on the menu option to open the generation window and launch the printout in the background. The procedure is then exactly the same as for creating a printout from the report overview.

5. Extended report options

Comment status in the validation report

In the validation report, the comment status for the respective item can now also be displayed. The list of options for the displayed properties next to the query status has been accordingly extended.

Printing query reports

For the query report, the printout for paper-based answers can be configured in advance in the FormBuilder. The options available in the validation printout have also been added here:

– Item value
– Separate section for signature

In the title row at the top right-hand side of every printout page, the printout title has been replaced with the current date.

In the signature line, the label for the first part has been changed to "Date" ("Place" has been deleted).

6. FormEngine

Metadata in rule conditions sT5.2-5.1, #8261, #8553

Metadata refers to information that describes the general environment of the currently open form. This includes (data type of the metadata value in brackets):

- Current centre (text)
- Current country (text)

  When using this metadata, please note that it is not mandatory to enter the country of the centre. It is therefore possible to leave out this value.
- Current visit (type)

  Every visit that has been defined in the project setup is an own data type and is used to create the patient visits. This type determines the visit label, which treatment arm it belongs to and the displayed forms.
- Current visit date (date)
- Current visit number (numbers)

  Visits are separated into scheduled and unscheduled visits in secuTrial® and then consecutively numbered and saved in the database in the order of their creation for a patient. In the case of non-chronological visits, the visit number may differ from the order of display.
- Current visit number according to type (numbers)

  The number of the current visit in the patient's visit plan, filtered by the current visit type (for unscheduled visits this is the same number as the current visit number because unscheduled visits are always numbered by type). This numbering reflects the chronological order of display, filtered by type.
- Current total number of visits (numbers)

  The total number of all visits for the current patient, regardless of visit type. This numbering reflects the chronological order of display.
- Current adverse event number (numbers)

  The adverse events are consecutively numbered in their order of creation.
- Current examination number (numbers)

  The examination number is based on the chronological order within the adverse event.
- Current adverse event date (date)
- Current examination date (date)
- Entry date of the patient (date)
- Pat-ID of the patient (text)
- Add-ID of the patient (text)
- Lab-ID of the patient (text)
- Current role (text)

  Displayed name of the current role of the logged in participant or patient.

Example visit plan numbering

The numbering of patient visits in secuTrial® is not always obvious. Here is a tabular overview of the numbering used (=number) and possible other values (=number by type, total number) for the metadata comparison.

Let's assume the project visit plan is as follows:

Day 0: "Screening" (scheduled)

Day 1: "Randomization" (unscheduled)

Day 8: "#-2nd treatment" (scheduled, can be repeated as many times as necessary)

"interim unscheduled visit#" (unscheduled, can be repeated as many times as necessary)

If we also assume the following visit plan was created for a patient, then this would result in the different numbering of the visits as follows:

Visit date	*Visit label*	*Number (saved value)*	*Number by type*	*Total number*
02/03/2016	"Screening"	1	1	1
03.03.2016	"Randomization"	2	1	2
10.03.2016	"1st treatment"	3	1	3
17.03.2016	"2nd treatment"	4	2	4
18.03.2016	"Interim visit 1"	1	1	5
19.03.2016	"Interim visit 2"	2	2	6
24.03.2016	"3rd treatment"	5	3	7

This metadata information can now also be selected in rule conditions as the parameter value; the options available for selection also depend on the type of form (current visit is only valid in a visit form).

Definition of rule conditions

In order to use metadata as a parameter value for a rule condition, the initial options available for selection have been extended to include the following (see highlight in Fig. 11):

- own item
- this item …
- this metadata value ...

If "this metadata value ..." is selected, the required metadata value must be chosen from the dropdown list. The other comparison options are then based on the data type of the selected metadata value. If "current visit" is selected, all visits created for the project can be selected (see Fig. 11, lower area).

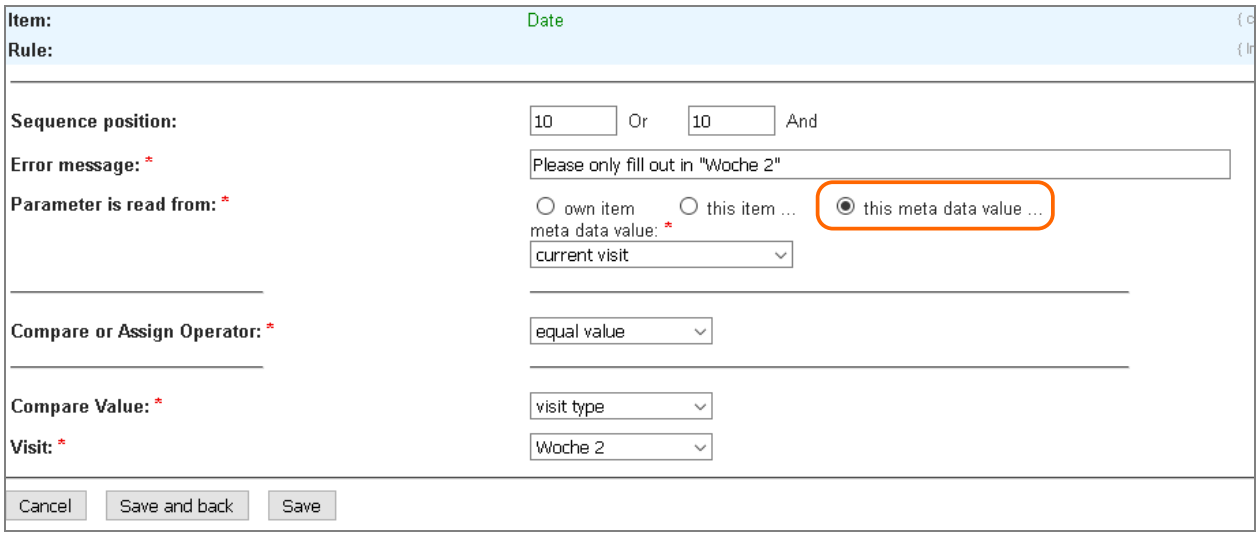

Fig. 11: Definition of rule condition with a metadata value as the parameter value (highlight: extended initial options for selection), in this case visit type.

Metadata can also be created as conditions for the hide rule (see Fig. 12).

Note: When using metadata conditions for role-based data entry, please note that – as always – values in hidden items are reset when the form is saved!

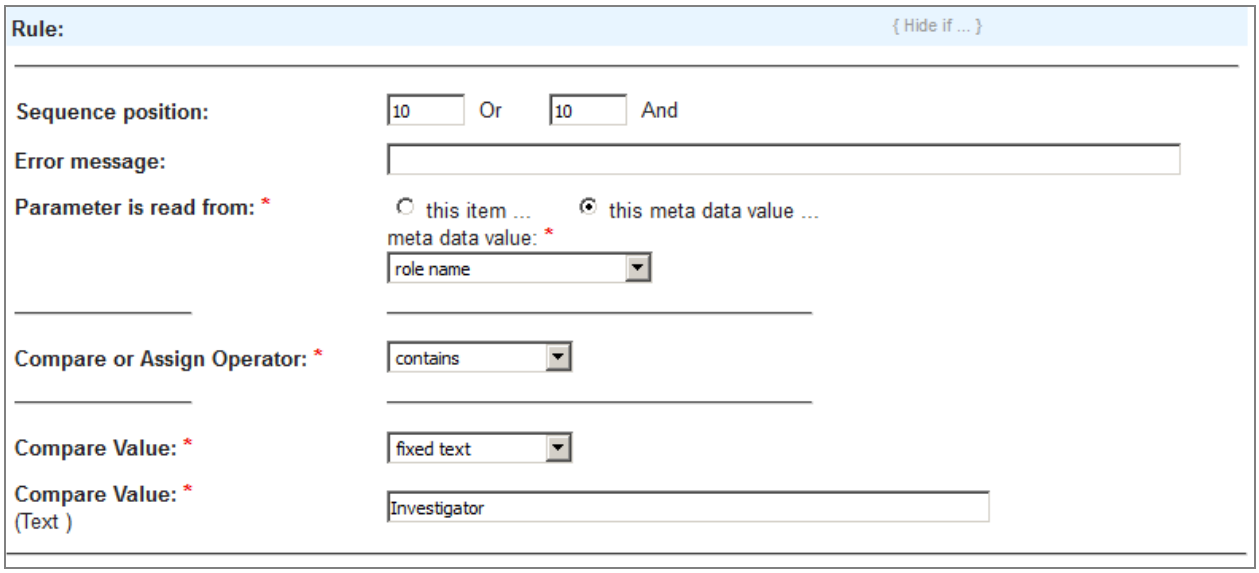

Fig. 12: Definition of rule condition with a metadata value as the parameter value, in this case role name.

Assigning values using rules

Metadata can also be used for assigning values by means of rules in a form item. The metadata value that can be assigned depends on the data type of the item:

- Text item:
  - Centre (name)
  - Country (name)
  - Visit (visit label)
- Number item:
  - Visit number
  - Visit number by type
  - Total visit number
  - Adverse event number
  - Examination number
- Date item:
  - Visit date
  - Adverse event date
  - Examination date
  - Entry date of the patient

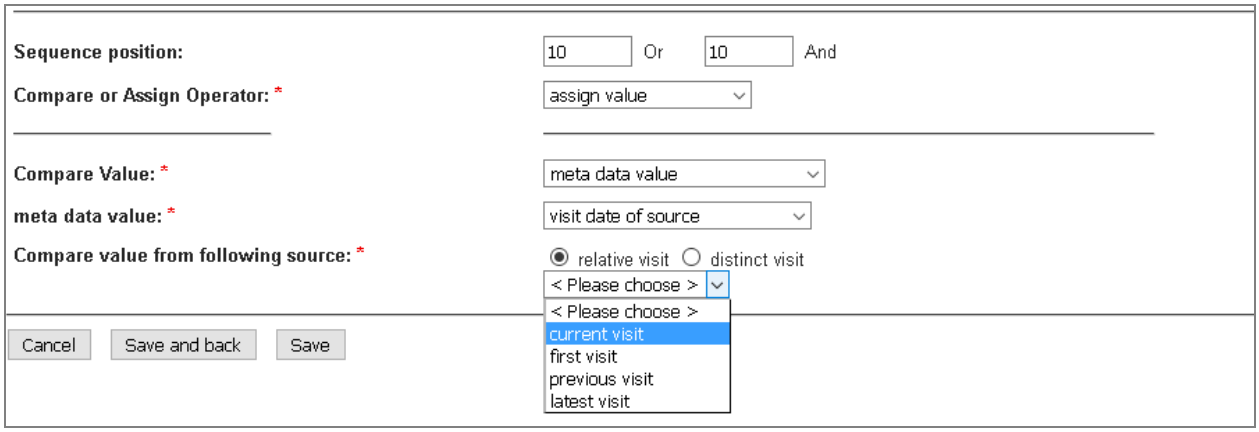

Fig. 13: Definition of the rule condition to assign a metadata value to an item.

Note: When using rules to assign text values (e.g. centre names), please note that the length of the texts which are being assigned cannot be checked in advance. The item should therefore be able to accommodate the maximum possible length of the text!

Assign a fixed value sT5.3-4.2, #5957

In previous versions, with “Take value from” rules it was only possible to select another item as the source for the value which is being assigned. “Take value from” rules are only executed when opening a form that has not yet been saved.

Now fixed values can also be selected as the source. The type of value depends on the data type of the respective item:

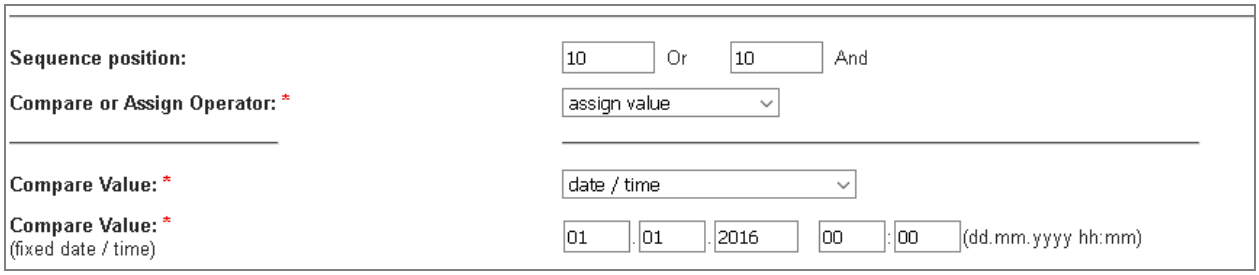

Fig. 14: Example: Definition of the rule condition to assign a fixed date to a date item.

Optimized user interface for rule preconditions #8784

To reduce the risk of confusing preconditions and execution conditions, the section for preconditions on the rule editing page in the FormBuilder tool is displayed as hidden (see Fig. 15). To create a precondition, this section can be expanded by clicking on the "Plus" icon or the title.

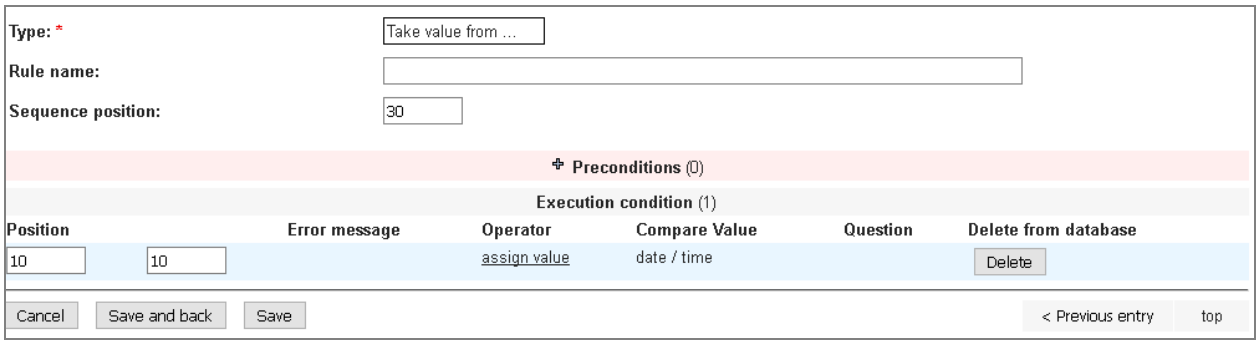

Fig. 15: Editing page (excerpt) for creating conditions for a “Take value from” rule.

If preconditions have already been created, they are always displayed and it is not necessary to expend the section. In contrast to the execution conditions, the preconditions now have a pink background instead of grey (see Fig. 16).

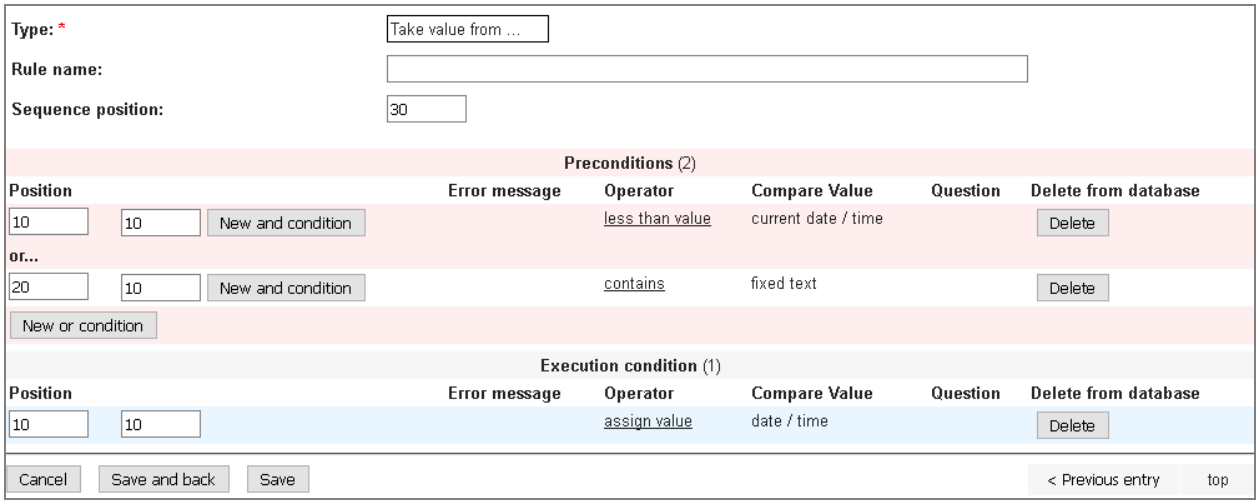

Fig. 16: Editing page (excerpt) for a “Take value from...” rule with already created preconditions.

Fixed issues

CustomerAdminTool

#8720 When editing the password file with the aid of the PwdManager in a Java console, it was not possible to change the password if one of the previous 5 passwords was entered as a new password. Although the action was performed without errors, the password was not changed.

This issue has been fixed. Attempts to change to a previous password are now rejected with an error message.

FormBuilder

#8641 The import configurations defined in a project that apply for the entire project and not just for individual forms were not contained in the project documentation dossier.

The import configurations are now listed in the project dossier before the form views.

#8642 In the mappings for an import format, the corresponding outer repetition group must be selected for all items in subforms. In the import format print view, the documentation for the selected repetition group was missing.

This issue has been fixed.

#8648 Import configurations and import formats could not be saved without entering a centre identifier, even if creating patients was not permitted (the centre is necessary for this).

This issue has been fixed. Entering a centre identifier is only mandatory if the user is permitted to create patients in the configuration or format.

#8853 Contrary to the other rules, the "Hide if ..." rule was called "Hide when ..." in English.

The rule has been renamed as "Hide if ..." in English.

AdminTool

#8692 The format for entering and displaying date values can be specified via the secuTrial® configuration files for the entire installation. When displaying the patient overview, the patient editing page and the project versions of the centres with CPV in the audit trail, the default format (dd.MM.yyyy) was always used instead of the configured format.

This issue has been fixed.

DataCapture

#8601 When defining external variables for an import format, it is not possible to enter empty spaces before or after the text. If the column headings had empty spaces on either side in the import file, the file could not be imported.

When importing CSV files, leading or trailing spaces are now always removed from column headings.

#8603 It was not possible to perform a mass import in an individual form (exception) if no identifier was defined in the selected import format.

This issue has been fixed.

#8805 If a warning before leaving a form without saving was configured in a project and an import was to be performed in an individual open form, the uploaded data could not be imported into the form because it was blocked by the warning window before leaving the form. The warning window was also hidden behind the import window.

This issue has been fixed. When importing uploaded data into the form no warning is displayed for leaving the form.

#8670 In the print view of the patient entry form for a project, all data entered in the form is listed in a text field separated by semicolons. If a confirmation of consent or consent date was configured for display in the form, neither of these were shown in the list.

This issue has been fixed. Both of these entries are now listed in separate columns if they are used in the entry form.

#8717 If a design was specified for a project that was different from the customer design, this design was not used when creating the patient file in PDF form. The customer design was always used.

This issue has been fixed.

#8863 After editing a form, the save message is displayed in an overlay above the form. For many forms, this overlay was moved to the final display position with a certain delay.

The overlay is now immediately displayed without delay in the final position.

Error corrections in 5.0.1

FormBuilder

#8804 The labels in the minimization randomization algorithm configuration for the "Probability" factor and the help text were not clear enough.

The German and English labels and help text have been optimised. The configuration option has been renamed to "Random Element".

#8854 When an individual form with configured double data entry (DDE) was imported into a project without the configured DDE function, It was no longer possible to edit the configuration even though it had not been set in the project.

When importing individual forms the DDE function for the forms is now reset if this function has not been activated for the project. The user is informed about this resetting after uploading the form setup.

#8899 There was a spelling error in an German error message for the editing of the visit plan.

The spelling has been corrected and the German and English wording has been optimized.

Error corrections in 4.9.1

DataCapture

#8837 When importing DICOM files via the Applet, the patient name and any ID information is replaced in the DICOM header with the patient's pseudonym. However, additional information in the header remained under the keys "OtherPatientNames" and "OtherPatientIDs".

Any entries in these keys are now also replaced with the patient's pseudonym.

Issues fixed during development

#8466, #8480, #8481, #8482, #8502, #8525, #8530, #8540, #8546, #8547, #8548, #8549, #8550, #8551, #8552, #8560, #8561, #8562, #8563, #8567, #8570, #8572, #8582, #8583, #8584, #8587, #8588, #8589, #8590, #8591, #8592, #8595, #8596, #8599, #8602, #8603, #8616, #8620, #8621, #8632, #8637, #8640, #8662, #8669, #8669, #8671, #8673, #8674, #8676, #8677, #8678, #8679, #8684, #8688, #8689, #8690, #8691, #8693, #8694, #8696, #8697, #8698, #8699, #8706, #8713, #8715, #8716, #8718, #8721, #8723, #8724, #8725, #8726, #8727, #8731, #8732, #8734, #8735, #8736, #8738, #8739, #8740, #8741, #8744, #8745, #8748, #8750, #8752, #8753, #8755, #8758, #8759, #8760, #8761, #8763, #8764, #8765, #8766, #8767, #8771, #8773, #8774, #8776, #8777, #8780, #8781, #8785, #8790, #8806, #8808, #8810, #8829, #8830, #8842, #8846, #8847, #8848, #8850, #8851, #8852, #8855, #8857, #8858, #8864

Deployment

Database

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

WOMonitor

In order to activate the export web services and to configure the session timout length of the web services, the following start parameters must be entered in the "Additional Arguments" field of required DataCapture:

Form data export:	`-DSRTFormDataExportService=true`
Project data export:	`-DSRTProjectDataService=true`
Web service session timeout (seconds):	`-DSRTWebServiceSessionTimeout=60`