



Documentation

secuTrial® Export Formats

Valid for Version 5.1

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1. Introduction

Data stored through the secuTrial® DataCapture may be exported to external files in various formats from the ExportSearchTool. The export is started by the user and generated asynchronous on the server. The file containing the exported data is at first stored on the application server. This file is encrypted for the intermediate storage using a five digit random TAN (transaction number) which is only known to the person who started the export. After completion of the export, the data file can be downloaded from the server using the TAN for access.

As the export generation is done asynchronous, you can start several exports, logout and login later to download the results. To get informed when the exports are finished you can be notified by e-mail.

All data of the patients entered in the eCRFs are exported. Further related data may be exported using the available options in the ExportSearchTool.

The data may be exported in various formats. These are:

- **SAS**
- **SPSS**
- **CSV / text files**
- **CDISC ODM**

All exported data are delivered as zip files to minimize download time. These files have to be unpacked before they may be imported into the required application.

The zip-files contain a varying amount of files:

- CDISC ODM v1.3 (XML): 6-9 files (1 *.xml for the data and 5-8 *.xsd file for description of formats)
- SAS: 1 *.sas, 1 *_fmt.sas file, all tables in separate files named *.dat in the subdirectory "dat".
- SPSS: 1 *.sps file, all tables in separate files named *.txt in the subdirectory "dat"
- CSV and text-format: all tables in separate files (forms and subforms, according audit trails-tables; additionally casenodes, forms, items, questions, visit plan, visit forms, centres, queries, comments, sdv, separate table with reference values [some might be missing according to the chosen export options])

Images

If the project setup and the chosen option ("Included data: project setup") includes separate image data as collected with an image item all exported files are included into a separate "patientimages" folder (with further substructure). The names and path of the included files are listed in the exported "images" table.

Images and image items are not included in the rectangular export format.

New features in secuTrial® 5.1

There are no changes regarding the export in this version.

1.1 Export Options

Several options can be set to define which data are to be exported. The range of options varies if the export is started directly or on the result of a search. It depends further on the project configuration and selected export format.

The selected options are included on a html page into the export zip file.

secuTrial® Date: 15.01.2016 - 14:22 (CET) Participant: Dipl. Biol. Susanne Schneider Time left: 59:25 | Welcome | Help | Logout

| Export | Export schedule | Download | Export history

New export

Description:

Project:

Centre: Bad Hersfeld

Visit: all visits first visit last visit selected visit

Patients: Valid patients All patients

Format:

Rectangular table

Duplicate form meta data into all tables

Column names

Store reference values: same table separate table

Shorten table name

Character encoding

Included data: Patient identifier: Pat-ID Add-ID

Centre information

Project setup

Queries and Comments

Source Data Verification

Missing Values

Audit Trail

Double Data Entry: undisplayed duplicates DDE not finished yet

Images: Original files Web files Thumbnail files

E-signature with validation

Form items: all items selected items

Form meta data:

Patient status

Structure

Document editing

Form status

Data handling: unselected checkbox as integer "0" "NULL" value

date/time values as: string (with spaces) real date/time with defaults

----- dd.mm.yyyy hh:mm:ss

Fig. 1: Upper page part of the possible options for exports (format CSV format for MS Excel).

Form items: all items selected items

Family 1

First examination <mpias1f2>

Base parameters

General examination

Will participate in study? <y>

Date of diagnosis <dt>

Age <age>

Height <height>

Weight <weight>

Randomisation

Form 2 <mpias1f6>

Family 2

CN Family

AE Family

Image

Fig. 2: Extended display for the selection of single or multiple items instead of all items to be included.

Patients which are to be deleted completely or from the selected project will never be exported regardless of the chosen options.

Format

There are 6 different export formats available:

- CDISC ODM v1.3 format (xml)
- SAS format
- SPSS format
- CSV format for MS Excel
- CSV data
- Text file with fixed field lengths

Depending on the chosen format more options are available to specify it: For normal CSV format the field separator and enclosure could be assigned, in the MS Excel format the tabulator is used as separator and double quotes as enclosure.

For the SAS and SPSS format additional files describing the data and starting the import in the statistical application are created. These files are intended to be executed in the evaluation program to load all exported data in one or two steps.

For both CSV formats and the text file the handling of the code list could be specified. The reference values could either be exported in a separate file or the codes could be directly replaced by the coded value in the same (form) table.

In the CDISC format some additional information could be included into the export by choosing the "with secuTrial® Extensions" option. The format of the single data item could be chosen between the current 1.3 and the older 1.2 ODM format. For further information see chapter: "CDISC ODM 1.3

- **Rectangular table**

For SAS, SPSS, CSV and TXT the rectangular format can be chosen. For each patient there will be exactly one data row with all forms. Repeated data e.g. forms shown in multiple visits will be exported as repeated columns. The repetition will be indicated by appropriate column names (see table description in section "6.24 data " below).

With this format all code lists are automatically included in the data table for CSV and TXT format. For the explanation of the column names there are always one or two additional tables included in the export. The visitplan (vp) explains the used visit IDs. The formnames (fa) are only needed in the SAS format and describes the replacement of the tablename with numbers, necessary because of the column name length restriction in this program.

- **Duplicate form meta data into all tables**

This option is not available for CDISC format and the rectangular option has not been chosen. The duplication of meta data will repeat all meta data specified below in the section "Included data" to be repeated in all patient-related tables when appropriate. The amount of repeated columns will also depend on the existing project setup. For example: when there is no randomization used in the project no randomization columns will be repeated (see explanation before the table descriptions for more details).

- **Shorten table names**

Normally all names (standard and eCRF tables) are appended by the project model suffix and the timestamp of the export, e.g. "casenode_TPX_20071105-183214.csv". For SAS tables the timestamp is only appended to the included *.dat files, not to the table names itself.

For the SAS, SPSS, CSV and TXT format the option "shorten table names" can be selected. In this case the standard tables are exported with only short names. Names of eCRF tables are abbreviated by removing the "mnp" and project model suffix from the table name. The prefix for audit trail and subform tables will be maintained.

WARNING: If there are any naming conflicts between custom and standard tables, the later exported tables will be renamed by adding a number suffix!

In the rectangular export format this option removes the timestamp from the name and shortens the names of the additional explanation tables. The project abbreviation remains.

Included data

■ Patient identifier

In all export files patients are identified by the internal unique patient identifier (=DB-primary key). Along with this identifier, the pseudonym and the additional identification code (=AID) to identify the patient in the export data may be exported. The possible choices depend on the project usage of these identifiers.

■ Centre information

Centre information may be included in the export data. The centre is exported in a separate table, containing the name of the centre and the country. For CDISC export this option is always enabled to create valid ODM files.

The participant information is now included with the document edit meta information (see below).

■ Project setup

A short description of the defined forms of the selected project including the project visit plan can be exported by choosing this option. For CDISC export this option is always enabled to create valid ODM files.

This option is not available for rectangular export formats.

■ Queries and Comments

Queries and Comments may be included in the export data.

This option is not available for rectangular export formats.

■ Source Data Verification (SDV)

The validation of the electronic data against the original source is stored in two separate tables (one for the current form data and one for the audit trail) which can be exported by choosing this option. The SDV status of each document is included into the export even if this option is not chosen. In the CDISC format the SDV status is added either as an additional attribute (with iAS extension) or as separate annotations (without iAS extension).

This option is only available if the usage of SDV is configured for the selected project. This option is not available for rectangular export formats.

■ Missing Values (MV)

The markup of missing values is stored in two separate tables (one for the current form data and one for the audit trail) which can be exported by choosing this option, the audit trail MV table only when the audit trail option is additionally selected. The markup of missing values is not exported within CDISC format.

This option is only available if the usage of MV is configured for the selected project. This option is not available for rectangular export formats.

■ Audit Trail

A complete audit trail may be exported along with the valid current patient data.

This option is not available for rectangular export formats.

■ Double Data Entry

This option is only displayed for projects which uses double data entry.

Normally only the original records where the double data entry comparison has been finished are exported. You can choose to include the duplicates (in the DataCapture visible from the original audit trail) or the double records before finished comparison to be included into export.

This option is not available for rectangular export formats.

■ Images

If any image item is included into the project setup these option let you include the original (uploaded), the displayed (web) and/or the thumbnail image to the export. Besides the image description table which is always exported, the option included the separate image files into the export. These files are exported in the separate "patientimages" folder.

This option is not available for rectangular export formats. Images and image items are not exported in the rectangular format.

- **E-Signature and validation**

Some information about the e-signature including the signature-validity of every eCRF may be included in the export data. The validation is done during the time of the export.

A new algorithm for creating e-signatures has been introduced in secuTrial® 3.1 to handle problems with signing subforms. The algorithm version is stored in each document to allow the validation of both (old and new) types of e-signatures. If the validation option has been choosen, this version is exported too.

This option is only available if the usage of e-signature is configured for the selected project.

- **Form data of hidden fields**

Instead of the deletion of items, questions or complete eCRFs with the risk of non-tolerable data-loss these elements can be marked as "hidden" in the FormBuilder. Even visit forms, not shown in any visit are treated as hidden. Hidden elements will not be displayed in the DataCapture for collecting and display of data but the data are preserved in the database and can still be exported (per selection for each export) and evaluated.

If the export option "include hidden data" is selected for export of SAS / SPSS / CSV or TXT format, even the data related to hidden fields will be exported. If any element in a project is marked as "hidden" the description of the project-setup contains an additional column for this property. The hidden data of the form description, queries, comments, sdv or forms will be marked as "hidden" in a therefore introduced column "hidden", resp. "mnphide" in form data tables.

In the CDISC format the form description and queries and comments on hidden elements are only exported if this option is chosen. Here the "hidden" property is exported as an annotation to the eCRF data. The form data are filtered as chosen by this option.

NOTE: It is not possible to export any data of visit forms not shown in any visit with the rectangular format because with this structure all forms must be assigned to a distinct visit to create the distinct columns!

- **Form items**

Since secuTrial 4.3 it can be selected weather the complete eCRFs or only selected items shall be exported. Non-displayed (=hidden) items can only be selected if the option "Form data of hidden fields" has been selected. Single items, formgroups, forms or formfamilies can be selected. At least one item must be selected to start an export with item selection.

In the non-rectangular export only those tables will be exported, that includes one of the selected items.

This option is not selectable for the CDISC format. For this format the complete project setup will always be exported.

- **Form meta data**

The meta information about form and patient status, document editing an eCRF-structure can be in- or excluded from the export. This can reduce the amount of additional columns if this information is not needed for data evaluation.

The specific description of the columns belonging to the meta categories can be found in the online help or in the annotations of the mnp* and data table descriptions below.

Data handling

- **Unselected checkbox**

The value of unselected checkboxes can exported as "0" (as in previous versions) or "null". In either cases it is not possible to distinguish between not stored eCRF with checkbox and stored eCRF with unselected checkbox values.

- **Date / time items**

To allow the handling of eCRF date / time items as real dates during evaluation it is now possible to let this value be exported in “real” date format. Because most evaluation software only accept complete dates and times, not given parts has be completed with a default value. The default can be specified here.

For further details about the exported date and time formats in the selected export format see the appropriate sections about “Date formats”.

- **Randomization**

If the project configuration includes the configurable randomization with blinding and the participant has the unblinding export right, there is an option to unblind the randomization during export. With this option selected the additional randomization columns in the casenode table (or the additional RANDOM form in the CDISC ODM format) will include the random groups whereas the normal randomization form items will always be exported the blinded randomization value.

The unblinding will be logged in the export history.

Filter data records

The included eCRFs are filtered by these options. A data row (one stored eCRF) will not be exported if the attributes stored in the congruent mnp-document (e.g. "form is complete") are not the same as specified in the filter options. The default value - “no check” – means not to filter by this option. The filter checks all options with an AND qualifier.

The options and values are:

- Completion status: no check / empty / partly filled / completely filled
- Validation: no check / without / with warning
- Validation: no check / without / with error
- Review A: no check / no / yes
- Review B: no check / no / yes
- Freeze (by system): no check / no / yes
- Comment status: no check / without / with comment
- Query status: no check / open / answered / resolved Query
- Source Data Verification: no check / not done / in progress / verified with errors / not necessary / verified

The filter applies to the current data in the eCRFs, if the audit trail option has been chosen, all audit trail records for all exported current records are exported. Therefore the actual status information of the audit trails records can be different from the filter selection.

Send email

You can be notified if the export has been finished. If your email contact is already known in secuTrial® the address field will be pre-filled.

1.2 Export after Search

Additionally search results can be exported. The data selection options "project" and "centre" are therefore not available, because the subjects whose data are to be exported are determined before the export is started on the result of the search.

Only patients displayed in the search result will be exported. That means the applied filters on the search result will apply on the export too. On the other hand all forms matching the export filter will be exported; the data is not restricted to that included in the search form.

Patients, who shall be deleted completely or in the chosen project, will never be exported.

2. Export Model

This section describes all possible tables and columns that SAS export files may contain. Some tables and columns are optional, see chapter: "Export Options".

2.1 Standard (non-rectangular) structure

For reasons of simplification, some tables in secuTrial® are joined into one table. Like this, the secuTrial® database model is transformed to a more flat model. The following picture illustrates the exported tables in a table-relationship model. A table is shown with its keys and major columns. The number of tables of entities "<tablename>", "<sub-tablename>" and "<at-tablename>", "<at-sub-tablename>" depends on the project (study).

Some of the tables could be omitted for an export depending on chosen export configuration. The columns in the "<tablename>" entities vary depending on the fact, if the eCRF has been collected during a normal visit, an adverse event or directly connected to the casenode. The exact declaration for these three categories can be found in the table descriptions.

The structuring into administrative data, study setup and eCRF data is only an informal structure concerning the table contents. This structure is not explicitly found in the export.

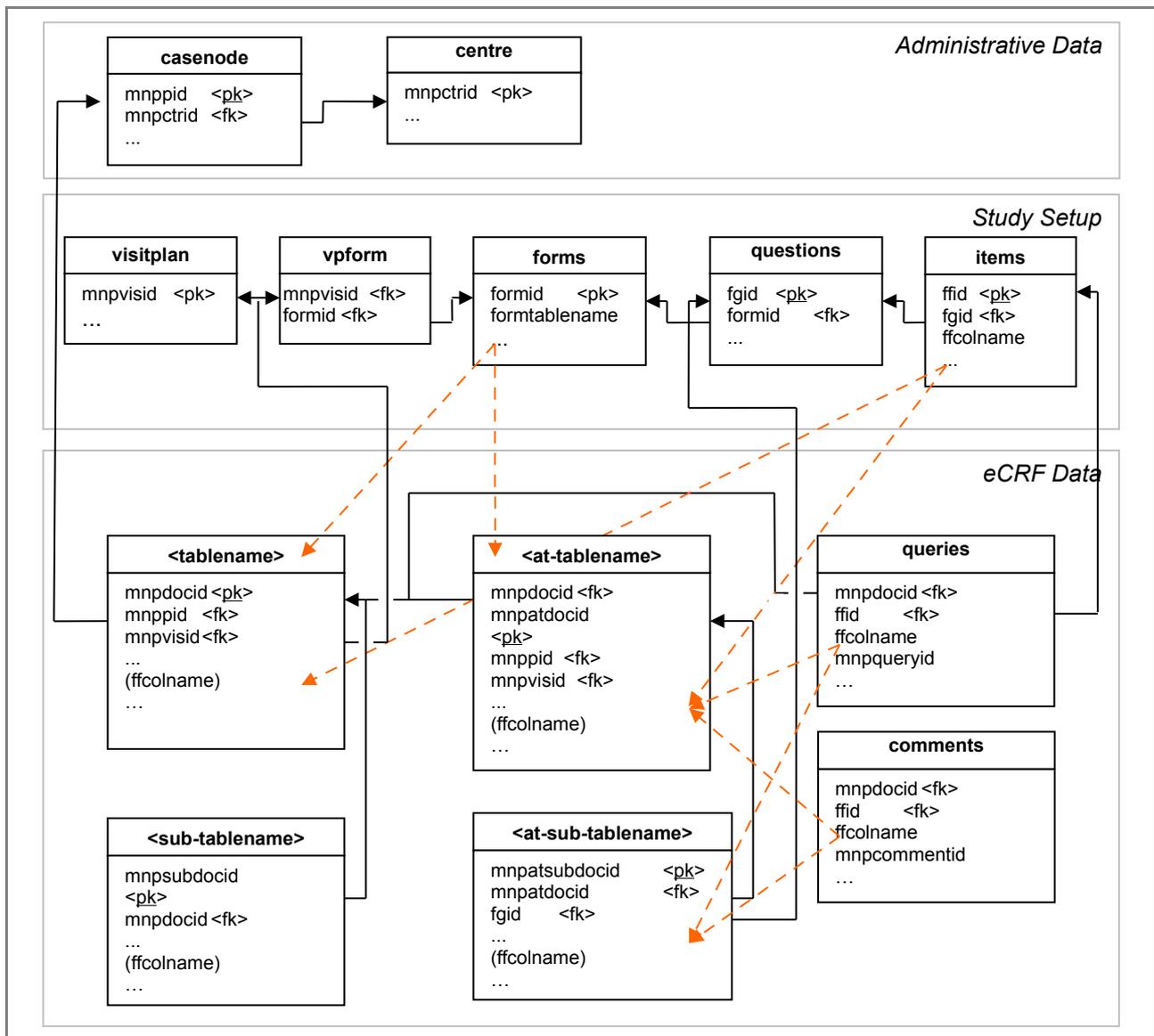


Fig. 4: Structure of the exported data in the standard (non-rectangular) format. The black arrows depict the relationships between the tables. The orange arrows indicate the content relations to the table and column names from the form setup to the eCRF data.

2.2 Rectangular structure

In the rectangular export format all casenode and eCRF data are exported into a single “data” table. For each patient there is exactly one data row. The tables structure of single eCRFs are then concatenated. Repeated display of forms, like eCRF shown in several visits, are then appended as additional columns.

The form types are concatenated in the sequence:

1. visit forms
2. casenode forms
3. adverse event forms
4. image forms

Patient visits are sorted by visit type as defined in the project visit plan. Visit repetitions are in immediate succession. Visit groups or treatment arms are neglected in the export. For each visit all shown forms are included.

Adverse events and follow-ups are repeated and counted according creation, starting with 1. For each follow-up all adverse event forms are included regardless if they are shown for a single patient (adverse event forms may be filtered according the “is SAE” property of the single event).

Image forms are also repeated and counted according creation per image form. The assignment to patients visit or follow-up are only indicated by the export of the corresponding *mnpcvpid* (=primary key of the patient-visit) or *mnpfuid* (primary key of the adverse event follow up). If both key columns are empty then the image form was assigned to the patient directly.

According to the form definition the user defined items are listed for each form. To distinguish the columns from separate eCRFs the columns are prepended by an appropriate name prefix. Subforms are repeated as often as the maximal number for each export. The item repetitions are marked by appending repetition indices (see below).

Scheme of column names for visit forms

Example: v21_1_mnntp0table_column[1_1]
 Visit: listed by primary key, here with visitid = 21
 Visit repetition: 1
 Table: mnntp0table ('mnp' + project scheme + user entered value), for SAS format the table names are replaced by a number to avoid too long column names. The replacement is documented in the *formnumbers* table.
 Column: column name as defined per user (eCRF item) or meta data (see table descriptions)
 Optional for sub forms: ID of Repetitiongroup-question and number of repetition

Scheme of column names for casenode forms

Example: c_mnntp0table_column[1_1]
 Table: mnntp0table ('mnp' + project scheme + user entered value)
 Column: column name as defined per user (eCRF item) or meta data
 Optional for sub forms: ID of Repetitiongroup-question and number of repetition

Scheme of column names for adverse event forms

Example: a1_3_mnntp0table_column[1_1]
 Adverse event number: counted by existence per patient, here = 1
 Repetition/Followup: counted by existence per patient, here = 3
 Table: mnntp0table ('mnp' + project scheme + user entered value)
 Column: column name as defined per user (eCRF item) or meta data
 Optional for sub forms: ID of Repetitiongroup-question and number of repetition

Scheme of column names for image forms

Example: i5_mnntp0table_column[1_1]
 Image form: repetition: 5
 Table: mnntp0table ('mnp' + project scheme + user entered value)
 Column: column name as defined per user (eCRF item) or meta data
 Optional for sub forms: ID of Repetitiongroup-question and number of repetition

If the option “shorten table names” have been selected, the “mnntp0” part of the form names are removed from the column names.

If an eCRF is not stored or created for a single patient the corresponding columns are empty. The structure of the complete table may differ depending on the included patient data: only the maximal number or repetitions in the exported data, not in the complete project data, are displayed.

For the explanation of the visit-IDs in the column names the standard table *visitplan* is additionally included in the export. In the SAS format the form table names are replaced by a simple form number. To explain the replacement an additional table *formnumbers* is exported too.

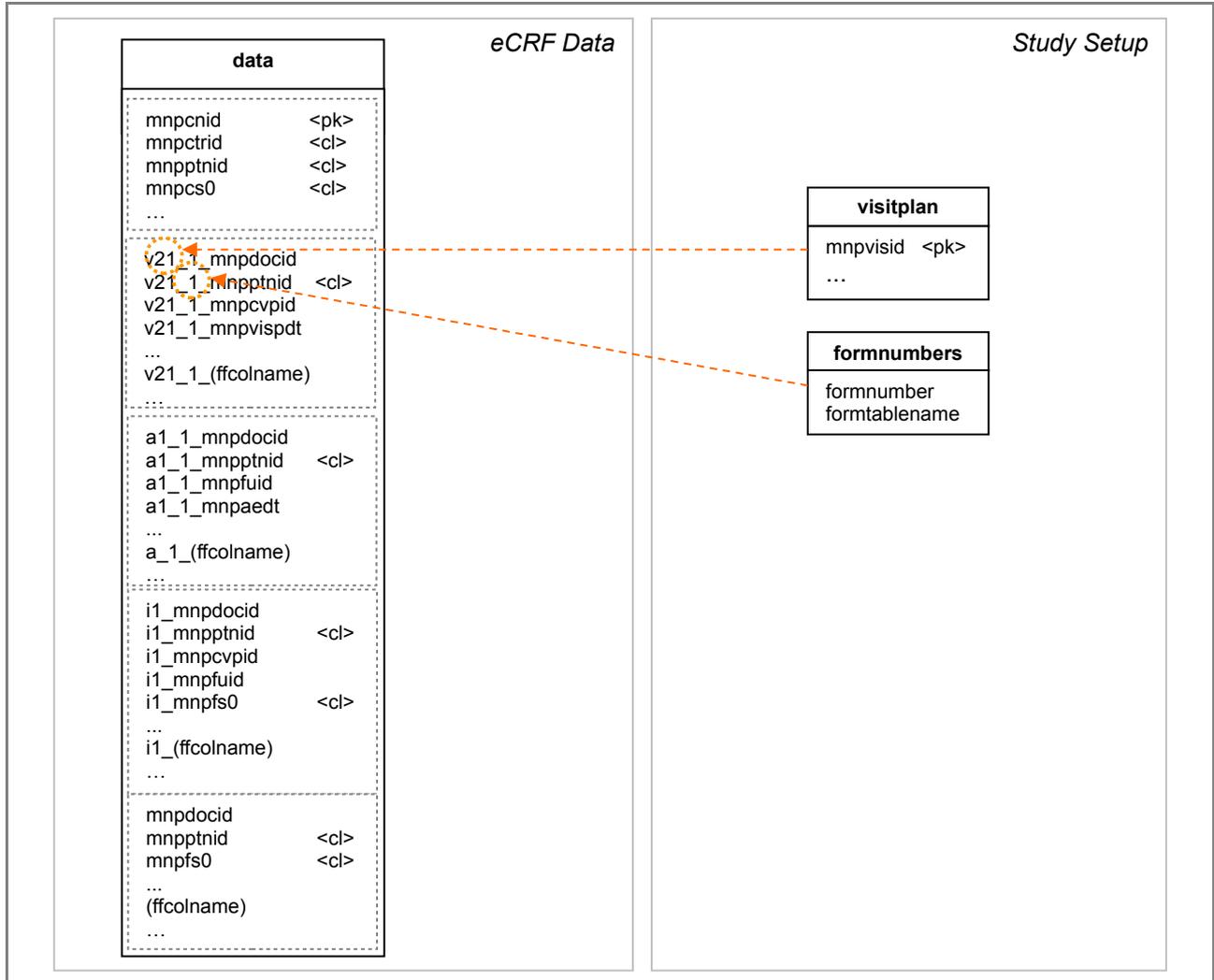


Fig. 5: Structure of the exported data in the rectangular. The orange arrows indicate the content relations to the name parts of the column names from the setup to the eCRF data. The table “formnumbers” is only exported in the SAS format, for all other formats the respective table names are used directly as part of the column names.

3. SAS-Format

3.1 Introduction

By selecting the appropriate export format, all data are exported in a SAS compatible format. At least two files are created for the export, one containing table meta-data and clinical data definition, the other containing the code lists. The naming convention for these files is: the file name is an abbreviation of the project name with the file extension ".sas". The code lists file has the additional naming extension "*_fmt.sas".

The sas file contains all data descriptions, the data records are separate files. All names of tables in the export have the name of table as they are stored in the secuTrial® database. These data tables are included in a separate directory "dat" and have the file extension ".dat". The names follow the convention:

- the prefix 'at' for audit records
- the prefix 'mnp' for normal data records, the prefix 'emnp' for repetition data records
- the project abbreviation, e.g. 'tp0'
- a representative short table name, e.g. 'persondata'

The naming of these files follows the naming convention described above, extended with the project abbreviation and the timestamp of the export, similar to the naming of the entire zipped download file. These names are referenced in the sas script file. This naming convention avoids mixing data from different exports.

Some older SAS versions only allow table names with eight characters. In order to achieve this, the coding convention prefixes apart from the prefix 'at' and 'e' (subforms) may be omitted from the export names, by using the export option "shorten table names".

The data descriptions have INPUT and ATTRIB definitions of all variables. The INPUT label defines the name of all variables in the record and the start position and the end position of data in the record. All alpha-numerical fields are identified with a dollar-sign (\$) before the start position. Date field input definitions are characterized by starting with an at-sign (@) followed by the start position of the date and then the field name.

The ATTRIB attributes contain a label for each variable, format details for code list elements, format and informat details for date variables.

In the rectangular export format there are exactly three data files: *data*, *visitplan* and *formnumbers*. The project abbreviation is always appended to the data files, an additional timestamp is appended if the option "shorten tablename" has not been selected.

3.2 Data types

Date Formats

All date fields edited in the eCRFs (IAS date components) are stored as strings in the database with the format YYYYMMDDHHMISS.

- YYYY is a four digit year value, e.g. 1956
- MM is a month as number (01 for January; 12 for December)
- DD is the day of the month
- HH is the time in 24 hours
- MI is the minute value of the time
- SS is the second's value of the time.

Other system generated dates are stored in a real data format in the database.

SAS has no data type for date times that is capable to specify the time zone. Two types of SAS date formats are used: DATETIME20 and DATE9. These formats are used to represent all internal dates stored in the system, such as last edit date, creation date, etc.

The time zone of all exported dates and datetimes is specified in the configuration file of the secuTrial® installation.

It is possible to export the item dates as “real” dates. Then they will be exported similar to the system generated date and times. For the display in SAS the FORMAT for these variables are specified to simulate the input display in the eCRFs. The “real” date formats are listed in the second row for each iAS date component.

If exporting as “real” date all values not entered in the eCRF are replaced by the defaults given during export start. It is not therefore not possible to distinguish if a user has left a minor part of a non-checked date item empty or if the part could not be entered because of the item type.

Type	iAS Format	SAS INFORMAT	SAS FORMAT	Format Description	Example
Date	(e.g visit date)	DATE11.	DATE9.	DD-MMM-YYYY	28-MAY-2004
Date-time	(e.g. last edit date)	DATETIME20.	DATETIME20.	DD-MMM-YYYY:HH:MI:SS	28-MAY-2004:11:58:03
iAS date components	YYYY	\$4		YYYY	2004
		DATE11.	YEAR4.	DD-MMM-YYYY	01-01-2004
	MM-YYYY	\$6		YYYYMM	200405
		DATE11.	MONYY7.	DD-MMM-YYYY	01-MAY-2004
	DD-MM-YYYY	\$8		YYYYMMDD	20040528
		DATE11.	DATE9.	DD-MMM-YYYY	28-MAY-2004
	DD-MM-YYYY HH:MM	\$12		YYYYMMDDHHMI	20040528115800
		DATETIME20.	DATETIME20.	DD-MMM-YYYY:HH:MI:SS	28-MAY-2004:11:58:00
	HH:MM	\$4		HHMI	1158
		TIME8.	HHMM5.	HH:MI:SS	11:58:00
	HH:MM:SS	\$6		HHMISS	115803
		TIME8.	TIME8.	HH:MI:SS	11:58:03
MM:SS	\$4		MISS	5803	
	TIME8.	TIME8.	HH:MI:SS	00:58:03	
iAS calculated date time intervals	Y	\$4		YYYY	0052
	Y-M	\$6		YYYYMM	001202
	Y-M-D	\$8		YYYYMMDD	00020503
	Y-M-D-H-M	\$12		YYYYMMDDHHMI	000205031205
	H-M	\$12		YYYYMMDDHHMI	000205031205
	H-M-S	\$14		YYYYMMDDHHMISS	00020503120512
	M-S	\$14		YYYYMMDDHHMISS	00020503120512

Because there are no display type for minutes and seconds only, this item type is formatted as a complete time if exported as “real” date.

Because of the three-letter month abbreviation it is possible to select the language for the date format. Probably most SAS installation will need the date-language in english.

Other Data Types

Other used SAS data types are Strings (\$8, \$10, \$20, \$40 ... \$100) and Numbers (4. == 4 digits).

The investigator data will be exported as code lists. In the rectangular data the centre and country information are also exported as code lists, in the standard format this information is exported in a separate table.

Most status data are exported as bit values which may be seen as Boolean values. The value 1 indicates that the bit is set and that the status is "valid" or "true". Status values "0" or NULL indicate that the bit is not set and that the corresponding status is "false". The meaning of all bit values are stored in the appropriate code list.

The data lines all have fixed length fields. Between each pair of fields, one field is left empty. This makes it easier to assess the file. Position rules with the variable names are provided as comments in the data file if configured via configuration file. This again is just a convenience to be able to examine the file manually.

Labels

Every table and each item of the form (which build the variable parts of the variables) have assigned a label taken from the form (=eCRF) declaration as done in the secuTrial® FormBuilder. The label of the whole eCRF is taken from the form name (the displayed name in the matrix).

The label of each item is made up of the item label. If this is not set, the question label is used. If this label is not set either, the unique label as for the search is used, which must be set at least.

Code Lists

Code lists are exported to a separate file with the name extension 'fmt'. The reference of which field has which code list is defined in the FORMAT value of the ATTRIB specifiers. The following items are exported as code lists:

- Status values. These are most binary values which only have one key/value pair for the value "1". Some status values are coded by a small amount of values.
- Checkbox values. Checkboxes may only be set or not set, like a binary value. In the data table, the value 1 represents "set". The coding of the value is stored in the code lists, and quite like the binary status values, may only have two key/value pair. The standard value is "yes" or "no". Per export option it is possible to export the non-set state as "null" (unset column = spaces).
- Drop down selections. All choices of the drop down are coded in the code list.
- Radio-button choices. All choices of a radio-button group are coded in the code list.
- Query, answer, comment, sdv code lists. The type of the annotation to an eCRF.
- Investigators. All investigators referenced in export data are coded in code lists. These are only exported if investigator and centre data are to be exported at all.
- Centre and country names. These are only exported for the rectangular format.

Images

With the image component files of any format can be uploaded to the server. This function is intended to be used to collect associated images to a study. Therefore besides storing the uploaded file on the server the system tries to generate a web image for display on the eCRF and a thumbnail for compressed display. All three images (if existent) can be included into the export and will be stored into a separate image folder.

As an eCRF item the image will be exported as a reference to the separate table "images" containing some information about the image as origin name, file size, file type, upload date and user who uploaded the image.

In the rectangular format image items and image data are not included, even if "all items" has been selected.

Numbers

In secuTrial® there are integer (without) and double (with decimal digits) number items. These items will be exported with the specified input precision.

Score number fields are exported with the length of 22 digits. The actual length of the calculated score number is nevertheless be the same as displayed length in the DataCapture and depends on the calculation algorithm and item configuration.

The used decimal digit character can be defined by specifying the number format language in the export options.

3.3 SAS Format Problems

Problem: Data lines in SAS longer than 256 are truncated at 256 bytes and an error may be generated see [<http://support.sas.com/techsup/unotes/SN/004/004448.html>].

To avoid this problem SAS advise to follow one of two options:

- Place data in an external file and specify this file in the INFILE statement. This allows the LRECL (logical record length, the maximum length of a record) to be specified. The appropriate length of each statement is calculated by secuTrial®.
- Alternatively, split the data lines, so that each line contains less than 256 bytes. This is not possible if the data fields themselves are longer than 256 bytes, for example with queries, answers and comments. However, data of lines that are longer than 256 bytes may be wrapped to the next line. This is indicated in the input statement of the SAS file by the line pointer control character "/".

Because text areas in secuTrial® can consist of more than the allowed length, only the first option is implemented since secuTrial® 2.0.

Since SAS version 9.1 it is possible to disable the option "QuoteLenMax" in the "fmt" script (export option "Ignore warnings for 262 character length"). Because the code list labels are originally not defined in SAS but in various secuTrial® places, they could exceed the SAS limitations.

4. SPSS Format

4.1 Introduction

The SPSS export consists of different files in one zip file with a similar structure as the SAS export. One *.sps syntax file describes the imported tables and columns and a "dat" folder contains the csv-data files.

The data files are simple csv-format as described in the next chapter. The single columns are enclosed in double quotation marks and are separated by single commas.

In the data files the column names are listed in the first line which is omitted during the syntax execution but can be used for manual inspections. In the syntax files the columns are labelled with the specified text for the SAS export (see table description for details) or the item labels as defined in the FormBuilder for the eCRF layout.

4.2 Data types

The medical data entered into the eCRFs are exported either as whole or rational number with defined length or as text. The length of text depends on the input field. The meta data information such as visit plan date or save timestamps are exported as real dates or datetimes. The length of number data are either defined by the number of the form item field for standard number fields or by constants used for coding values.

Date formats

It is possible to export the item dates as "real" dates. Then they will be exported similar to the system generated date and times. For the display in SPSS for these variables FORMATS are specified to simulate the input display in the eCRFs. The "real" date formats are listed in the second row for each iAS date component.

If exporting as "real" date all values not entered in the eCRF are replaced by the defaults given during export start. Therefore it is not possible to distinguish if a user has left a minor part of a non-checked date item empty or if the part could not be entered because of the item type.

The time zone of all exported dates and datetimes is specified in the configuration file of the secuTrial® installation.

Type	iAS Format	SPSS INFORMAT	SPSS FORMAT	Format Description	Example
Date	(e.g. visit date)	DATE	DATE9.	DD-MMM-YYYY	28-MAY-2004
Date-time	(e.g. last edit date)	DATETIME	DATETIME23.2.	DD-MMM-YYYY HH:MI:SS	28-MAY-2004 11:58:03
iAS date components	YYYY	A4		YYYY	2004
		DATE	MOYR9	DD-MMM-YYYY	01-01-2004
	MM-YYYY	A6		YYYYMM	200405
		DATE	MOYR9	DD-MMM-YYYY	01-MAY-2004
	DD-MM-YYYY	A8		YYYYMMDD	20040528
		DATE	DATE11	DD-MMM-YYYY	28-MAY-2004
	DD-MM-YYYY HH:MM	A12		YYYYMMDDHHMI	20040528115800
		DATETIME	DATETIME23.2.	DD-MMM-YYYY HH:MI:SS	28-MAY-2004 11:58:00
	HH:MM	A4		HHMI	1158
		TIME	TIME5	HH:MI:SS	11:58:00
	HH:MM:SS	A6		HHMISS	115803
		TIME	TIME8.	HH:MI:SS	11:58:03
	MM:SS	A4		MISS	5803
		TIME	TIME8.	HH:MI:SS	00:58:03

Type	iAS Format	SPSS INFORMAT	SPSS FORMAT	Format Description	Example
iAS calculated date time intervals	Y	A4		YYYY	0052
	Y-M	A6		YYYYMM	001202
	Y-M-D	A8		YYYYMMDD	00020503
	Y-M-D-H-M	A12		YYYYMMDDHHMI	000205031205
	H-M	A12		YYYYMMDDHHMI	000205031205
	H-M-S	A14		YYYYMMDDHHMISS	00020503120512
	M-S	A14		YYYYMMDDHHMISS	00020503120512

Because there are no display type for minutes and seconds only, this item type is formatted as a complete time if exported as "real" date. There is no FORMATS type in SPSS for year only, so this item type is formatted similar to the month-year item.

Because of the three-letter month abbreviation it is possible to select the language for the date format. Probably most SPSS installation will need the date-language in english.

Code Lists

Coded values such as radio button, popup, lookups, checkboxes as well as status values and participant references are exported as coded values with defined value labels containing all corresponding possible values.

The following items are exported as code lists:

- Status values (F2.0)
These are most binary values which only have one key/value pair for the value "1". Some status values are coded by a small amount of values. The length for this fields are F2.0
- Checkbox values (F2.0)
Checkboxes may only be set or not set, like a binary value. In the data table, the value 1 represents "set". The coding of the value is stored in the code lists, and quite like the binary status values, may only have two key/value pair. The standard value are "yes" and "no".
- Drop down selections ("popup" items)(F10.0)
All choices of the drop down are coded in the code list.
- Radio-button options (F10.0)
All options of a radio-button group are coded in the code list.
- Query, answer, comment, sdv status code lists (F2.0)
The type of the annotation to an eCRF.
- Investigators (F10.0)
All investigators referenced in export data are coded in code lists. These are only exported if investigator and centre data are to be exported at all.
- Centre and country names (F10.0). These are only used for the rectangular format.

Images

With the image component files of any format can be uploaded to the server. This function is intended to be used to collect associated images to a study. Therefore besides storing the uploaded file on the server the system tries to generate a web image for display on the eCRF and a thumbnail for compressed display. All three images (if existent) can be included into the export and will be stored into a separate image folder.

As an eCRF item the image will be exported as a reference to the separate table "images" containing informations about the image as origin name, file size, file type, upload date and user who uploaded the image.

In the rectangular format image items and image data are not included, even if “all items” has been selected.

Numbers

The number format in SPSS depends on the system locale of the SPSS installation. As this could be set during the import it would change the setting permanently. So the number format can be chosen before the export creation in secuTrial® independently of the module or project configuration to match the SPSS system used for evaluation.

5. CSV & Text Formats

5.1 Introduction

The CSV-Format (Character Separated Values) is a very flexible export format, and many systems support their import: Microsoft Excel, OpenOffice.org Calc, Oracle, SPSS. A disadvantage of this format against SAS and CDISC is that no meta-data such as labels and descriptions of fields may be exported. The CSV and Text formats are described together here. They only vary slightly in the formatting of the data lines.

Three export selections are available for these formats:

- CSV Format for MS Excel
- CSV Data
- Text files with fixed field lengths.

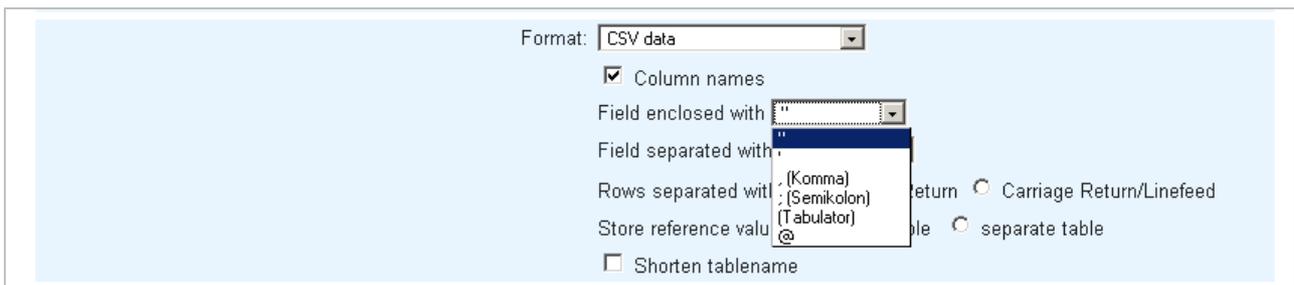


Fig. 6: Possible encloser types for the CSV export format.

The CSV formats use variable field lengths. The data fields are enclosed with field enclosure characters and are delimited by another character. The MS-Excel format uses a tabulator "(Tabulator)" as field separator and double quotation marks as field enclosure characters. In the CSV data format these delimiters may be altered (see possible selection as shown above). In the text file format with fixed field lengths, all fields are exported with fixed field lengths and no field delimiters are used, similar to the SAS dat-file format.

Each table is exported to a separate file. The file name has the name of the table. Reference values may be exported to separate tables or to the same table. When exported to the same table, the code is replaced. If exported to a separate file, they are all exported to one file, with the naming convention „cl_“+ project abbreviation.

Column names may be exported; these will be exported to the first line of each file.

5.2 Data types

Date Formats

It is possible to export the item dates as “real” dates. Then they will be exported similar to the system generated date and times. The “real” date formats are listed in the second row for each iAS date component. It is not possible to specify a distinct display format in CSV or TXT files. This has to be done manually in the used software if desired.

If exporting as “real” date all values not entered in the eCRF are replaced by the defaults given during export start. It is not therefore not possible to distinguish if a user has left a minor part of a non-checked date item empty or if the part could not be entered because of the item type.

The time zone of all exported dates and datetimes is specified in the configuration file of the secuTrial® installation.

Type	iAS Format	Format Description	Example
Date	(e.g visit date)	YYYY-MM-DD	2004-05-28
Date-time	(e.g. last edit date)	YYYY-MM-DD HH:MI:SS	2004-05-28 11:58:03
	YYYY	YYYY	2004

Type	iAS Format	Format Description	Example
iAS date components	MM-YYYY	YYYY-MM-DD	2004-05-28
		YYYYMM	200405
		DD-MMM-YYYY	2004-05-28
	DD-MM-YYYY	YYYYMMDD	20040528
		DD-MMM-YYYY	2004-05-28
	DD-MM-YYYY HH:MM	YYYYMMDDHHMI	20040528115800
		DD-MMM-YYYY HH:MI:SS	2005-05-28 11:58:03
	HH:MM	HHMI	1158
		HH:MI:SS	11:58:00
	HH:MM:SS	HHMISS	115803
		HH:MI:SS	11:58:03
	MM:SS	MISS	5803
		HH:MI:SS	00:58:03
iAS calculated date time intervals	Y	YYYY	0052
	Y-M	YYYYMM	001202
	Y-M-D	YYYYMMDD	00020503
	Y-M-D-H-M	YYYYMMDDHHMI	000205031205
	H-M	YYYYMMDDHHMI	000205031205
	H-M-S	YYYYMMDDHHMISS	00020503120512
	M-S	YYYYMMDDHHMISS	00020503120512

Code Lists

Code lists could be exported to a separate file with the name "cl_" + project-abbreviation if the option "separate table" is chosen. Otherwise the db-values of code lists would be replaced by the referenced (label-) values during export. The three columns contain information about "column", "code", and "value". The column is described by table name + "." + column name. The code consists of the db-value to be interpreted, and the value represents the meaning of the code. The following item types are referenced in the code list:

- Binary status values. These only have one key/value pair for the value "1".
- Status values for status with more than one option.
- Checkbox values. Checkboxes may only be set or not set, like a binary value. In the data table, the value "1" represents "set". The coding of the value is stored in the code lists and like the binary status values may only have two key/value pair. The value is "yes" or "no" possibly appended by label following the checkbox display in the form.
- Drop down selections. All choices of the drop down are coded in the code list.
- Radio-button choices. All choices of a radio-button group are coded in the code list.
- Queries, sdv: The type of annotation to an eCRF.
- Investigators. All investigators referenced in export data are coded in code lists. These are only exported if investigator and centre data are to be exported.

If an item references a lookup table and the reference values are exported into separate files the values of the lookup table are referenced by this lookup table name in contrast to simple code list values of radio buttons which are referenced by table- and column name of the item. The information which lookup table has to be used for an item is given in the "lookuptablename" column of the item-description.

With the rectangular table format the option "separate table" cannot be chosen and all values will be directly exported inline in the data table.

Images

With the image component files of any format can be uploaded to the server. This function is intended to be used to collect associated images to a study. Therefore besides storing the uploaded file on the server the system tries to generate a web image for display on the eCRF and a thumbnail for compressed display. All three images (if existent) can be included into the export and will be stored into a separate image folder.

As an eCRF item the image will be exported as a reference to the separate table "images" containing some information about the image as origin name, file size, file type, upload date and user who uploaded the image.

In the rectangular format image items and image data are not included, even if "all items" has been selected.

Numbers

The number format can be chosen before the export creation in secuTrial® independently of the module or project configuration to match the software system used for evaluation.

6. Table descriptions

The following table description generally applies in structure and content to the SAS, SPSS and the CSV / TXT formats. The **Label** descriptions are only applicable for the SAS or SPSS export format. The **SAS Length/ Format** description is only applicable for the SAS export format. The **SPSS Format** descriptions are only applicable for the SPSS export format.

For simple **CSV** or **TXT** format only the variable names are exported and even that only if the corresponding option ("column names") has been chosen.

6.1 Explanations for variable description flags

The numerical or letter flags in the first columns of the export table descriptions mark variables that are only exported if project configuration and export options match specific criteria. These flags are explained here.

0: Patient's pseudonym

This variable includes one of the patient's pseudonym. The available pseudonyms depend on the project's configuration. The available pseudonyms can be selected separately to be included.

1: Centre information

This variable is only exported if the export option "Centre information" has been chosen.

2: Document editing

This variable is only exported if the export option form meta data "Document editing" has been chosen. It contains information about author (investigator or patient user) and edit date. The variable for the patient user is only exported if the project uses the "patient reported outcome" (PRO) workflow. In that case either participant or patient could have made one entry. In that case for each line either participant or patientuse will be set, not both.

3: Structure information

This variable is only exported if the export option form meta data "structure information" has been chosen. This information includes event (visit / adverse event) dates or event numbering.

v: Visit or image eCRF

Visit eCRFs additionally have these variables of the Case Visit Plan of every patient. The labels of the visits and other meta-data are exported in a separate table, see [section Visit Plan].

As image eCRFs could be related to either patient, single visits or adverse event follow-ups these tables will have all possible visit columns too.

a: Adverse Event or image eCRF

Adverse Events are occasions when a patient visits the physician for a medical reason outside of the regular visit plan of the trial (according GCP: "Any untoward medical occurrence in a patient or clinical investigation subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment."). The indication of the irregular visit, for example *flu*, is the Adverse Event. All further irregular visits to the physician for the same indication are follow-ups to the initial Adverse Event.

As image eCRFs could be related to either patient, single visit or adverse event follow-up these tables will have all possible adverse event columns too.

i: Image eCRF

Image eCRFs did not follow a study plan. They can be created using the predefined forms by every participant with the edit right and can be related to patient, visit or adverse event follow-up. These variables define the creator (participant) and creation date.

4: E-Signature and validation

This variables are only exported if the e-signature is used and the option "E-signature with validation" has been chosen.

5: Hidden data

This variable is only exported if there are any hidden fields in the project and the option "Form data of hidden fields" has been chosen.

6: Patient status

This variable is only exported if the export option form meta data "patient status" has been chosen.

7: Form status

These variables are only exported if the export option form meta data "status" has been chosen. They contains information about the completion and review status of a form document.

8: Image files

These variables includes the file names of the included image (binary) files. Which of the three possible files (original, web-display, thumbnail) are included depends on the distinct selection. If a value could be exported depends on the file's type (only real images can be manipulated to create a web display and thumbnail image).

d: Double data entry

This variable is only exported if there is any double data entry form in the project.

m: Duplication of meta data

This variables will only be exported if the additional format option "Duplicate meta data in all tables" has been chosen. This variables are also restricted by the other options listed above.

r: Randomization

This variable(s) is (are) only exported if the project contains any configurable randomization. The variable name and label of this information depends on the definition of the randomization button item. The variable for the random number ('no') is only added if the randomization is blinded. The "rdm" part of the column name is replaced by the random column name specified in the randomization form.

t: DTM

This variable is only exported if the workflows of the project include the discrepancies handling (DTM).

p: Patient information

For form tables: This variable is only exported if the table includes patient form related information only.

c: Centre information

This variable is only exported if there are any centre forms specified in the project and the table either contains centre form data or the content could be related to patient or centre form data (e.g. for queries).

6.2 visitplan /vp (Project visit plan)

This table is exported if the option "Project setup" was included. The primary key of the visit ('mnpvisid') is referenced in every visit related eCRF.

This table is always exported in the rectangular format as an explanation for the the column visit numbers.

In the productive area the visitplan of the current, productive project and all archived project versions are exported, the version information is included in the last two columns. In the setup area these columns will be empty. Only if a project has just been set to released but the release has not been performed the version information of the next productive version is included there.

<i>Variable</i>	<i>Label</i>	<i>SAS Length/ Format</i>	<i>SPSS Format</i>	<i>Description</i>
mnpvisid	Visit-ID	10	F10.0	Identifier of the visit. Used in eCRF Data as reference to the Visit Plan.
visitnumber	Visit sequence	10	F4.0	Sequence of visit creation
visitype	Type of visit	2 [clvt.]	F2.0	Type of visit (scheduled/unscheduled, type of date check) [0 = 'fixed' 1 = 'flexible' 2 = 'unscheduled' 3 = 'free']

	Variable	Label	SAS Length/ Format	SPSS Format	Description
	previsid	Preceding visit-ID	10	F10.0	Reference to the preceding visit (needed for calculation of visit date)
	visitday	Time lag to preceding visit (days)	10	DATE11	The visit plan date is calculated by the date from the preceding visit (see above) and this time lag.
	minusoffset	Possible negative time frame (days)	10	F10.0	For some visit types it is possible to give a time frame around the calculated visit day where a visit is allowed. This defines the days before the visit plan date.
	plusoffset	Possible positive time frame (days)	10	F10.0	For some visit types it is possible to give a time frame around the calculated visit day where a visit is allowed. This defines the days past the visit plan date.
	visitarm	Treatment arm	\$100	A100	Name of the treatment arm if this visit is dedicated to an arm.
	visitgroup	Visit group	\$100	A100	Name of the visit group if this visit is included into a (repeated) visit group.
5	hidden	hidden in DataCapture	2 [chd.]	F2.0	A status setting indicating that this visit is hidden in the DataCapture. [0 = 'no' 1 = 'yes']
	mnpvislabel	Visit label	\$50	A50	(Individual) visit label that is shown in the patient's form overview.
	mnpvsno	Version number	10	F10.0	Version number of project (will only be set in productive area).
	mnpvsbl	Version label	\$30	A30	Version label of project (will only be set in productive area)

6.3 visitplanforms / vpfs (Forms shown in visits)

This table is exported if the option "Study setup" was included. It only consists of the two foreign keys of visit and form, indicating which form is presented in which visit. This can be used to check if every presented form is stored for a patient.

Variable	Label	SAS Length/ Format	SPSS Format	Description
mnpvisid	Visit-ID	10	F10.0	Identifier of the visit. Used in eCRF Data as reference to the Visit Plan.
formid	Form-ID	10	F10.0	Identifier of the Form-Definition.

6.4 forms / fs (Forms)

All forms are exported to one table. This is exported if the option "Project setup" was included.

An eCRF in secuTrial® is based on a form definition which is set up in the FormBuilder and stored in the database too. A short form setup description is exported too in three tables: "forms", "questions" and "items". The eCRF setup is structured hierarchically: 'form' <--> 'question' <--> 'item'. One eCRF is described with one form (and stored into one db table). The questions are mainly for layout purpose but connect also to the subforms. The items itself reflects the single db column. In queries and comments the items are referenced by id and Colum name.

For subforms the question-ID of the parent-repetition is exported to distinguish between double referenced subforms in the same parent form (e.g. medication in the morning and medication in the evening, recorded in one form "medication").

The 'hidden' column is only present for projects which contain at least one 'hidden' element (either form, question or item).

In the productive area the forms of the current, productive project and all archived project versions are exported, the version information is included in the last two columns. In the setup area these columns will be empty. Only if a project has just been set to released but the release has not been performed the version information of the next productive version is included there.

The variables for forms are:

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	formid	Form-ID	10	F10.0	Unique identifier of the form.
	formtablename	DB table name	\$24	A24	The table name for the form-data. This table name is used in the export as the (part) filename too.
5	hidden	hidden in DataCapture	2 [clhd.]	F2.0	A status setting indicating that this form is hidden in the DataCapture [0 = 'no' 1 = 'yes']
	formname	Form name (as in matrix)	\$200	A100	This name is used in the patient matrix to identify an eCRF. Most times it will be the same as the title of the opened eCRF.
	formfamily	Form family name	\$100	A100	Name of the form family as displayed in the matrix.
	sequence	Form sequence in form family	10	F10.0	Sequence of form in the form family. This field is used for numerical sorting.
d	ddetype	DDE form type	2 [cldde.]	F2.0	A flag indicating that this form is used as a double data entry form. [0 = 'normal form' 1 = 'DDE form']
	mnpvsno	Version number	10	F10.0	Version number of project (will only be set in productive area).
	mnpvsbl	Version label	\$30	A30	Version label of project (will only be set in productive area).

6.5 questions / qs (Questions)

This table is exported if the option "Project setup" was included. Questions are the intermediate level between forms and items. This level is used in secuTrial® mostly for layout purpose. Often it does contain the question text of the eCRF.

The 'hidden' column is only present for projects which contains at least on 'hidden' element (either form, question or item).

The variables for questions are:

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	fgid	Question-ID	10	F10.0	Unique identifier for the question. This ID is referenced in the QAC table.
	formid	Form-ID	10	F10.0	Identifier of the form, foreign key to the forms table.
	formtablename	DB table name	\$24	A24	The table name for the form-data. This table name is used in the export as the (part) filename too.

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	forname	Form name (as in matrix)	\$200	A100	This name is used in the patient matrix to identify an eCRF. Most times it will be the same as the title of the opened eCRF.
	sequence	Question sequence in form	10	F10.0	Sequence of question in the form as used for sorting. This may not be filled or may not simply be incremented. This field is nevertheless used for numerical sorting.
5	hidden	hidden in DataCapture	2 [clhd.]	F2.0	A status setting indicating that this form is hidden in the DataCapture. [0 = 'no' 1 = 'yes']
	fglabel	Question label (or unique label for search)	\$200	A200	The text of the question in the form. If this is not set, the unique label for search is used (which must be set at least in the FormBuilder)
	subform- tablename	Sub-form DB table name	\$24	A24	The table name for the subform data. This column is only filled for repetition form groups.

6.6 items / is (Items)

This table is exported if the option "Study setup" was included. All Items are exported to one table. One item corresponds to a single data field in the eCRF. Sometimes the textual descriptions are stored in the question label (see above); therefore the exported label could be the same as the label of the question itself.

The 'hidden' column is only present for projects which contains at least on 'hidden' element (either form, question or item).

The variables for items are:

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	ffid	Item-ID	10	F10.0	Unique identifier for the item.
	fgid	Question-ID	10	F10.0	Identifier for the question, foreign key to questions. This ID is referenced in the QAC table.
m	fglabel	Question label (or unique label for search)	\$200	A200	The text of the question in the form. If this is not set, the unique label for search is used (which must be set at least in the FormBuilder)
m	formid	Form-ID	10	F10.0	Identifier of the form, foreign key to the forms table.
m	formtablename	DB table name	\$24	A24	The table name for the form-data. This table name is used in the export as the (part) filename too.
m	forname	Form name (as in matrix)	\$200	A100	This name is used in the patient matrix to identify an eCRF. Most times it will be the same as the title of the opened eCRF.
	sequence	Item sequence in question	10	F10.0	Sequence of items in the question as used for sorting. This may not be filled or may not simply be incremented. This field is nevertheless used for numerical sorting.
	ffcolname	DB column name	\$32	A32	Identifier of the form, foreign key to the forms table.

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	itemtype	Item component type	\$200	A200	The name of the assigned item component type.
5	hidden	hidden in DataCapture	2 [clhd.]	F2.0	A status setting indicating that this form is hidden in the DataCapture [0 = 'no' 1 = 'yes']
	fflabel	Item label (or question label or unique label for search)	\$1500	A1500	The text of the item in the form. If this is not set, the question label or at least the unique label for search is used (which must be set in the FormBuilder)
	unit	Unit / additional text	\$200	A200	This text is displayed after the input element. It often describes the measurement unit of a number variable.
	lookuptable	name of lookup table	\$30	A30	If the column refers to it the name of the Lookup table is inscribed
d	ddecomp	Comparison type for DDE	2 [clddecomp.]	F2.0	A status describing the type of comparison for DDE. [null/0 = 'compare' 1 = 'ignore' 2 = 'ignore case and whitespace' (only text) 3 = 'compare including hash values' (only images)]

6.7 deactivatedcodes / dc (Deactivated Codelists Options)

This table is exported if the option "Project setup" was included. This table is only exported if there are any deactivated code list entries at all in the project or the exported data. This table describes which code list options are deactivated and in which project version this was done. Code list items are either of type radio button, popup or lookup.

The variables for deactivated code list options are:

Variable	Label	SAS Length [Format]	SPSS Format	Description
codelist	Code list	\$30	–	Name of the code list. This column is only exported in the SAS format because all other formats do not use code list names.
formtablename	DB table name	\$25	A24	The name of the form (for radio button and popup items).
column	Column	\$30	A30	The name of the form column (for radio button and popup items).
lookuptable	Name of lookup table	\$30	A30	The name of the lookup table (for lookup items).
value	Value	10	F10.0	Coded value of code list entry.
label	Label	\$200	A200	Label of the code list entry.
version	Version	\$100	A100	Version label of the project where the entry was (last) deactivated.
versiondate	Version date	DATETIME20	DATETIME23.2	Version timestamp of the project where the entry was (last) deactivated.

6.8 centres / ctr (Centres)

This table is exported if it is chosen to export "Investigator and centre" option. All centres of the project are exported. The primary key of the centre "mnpctrid" is then referenced in every casenode.

The variables for centres are:

Variable	Label	SAS Length [Format]	SPSS Format	Description
mnpcntrid	Centre-ID	10	F10.0	The identifier of the centre.
mnpcntrname	Centre name	\$100	A100	The name of the centre.
mnpcname	Country name	\$200	A200	The name of the country.

6.9 casenodes / cn (Patient information)

This table contains the basic information about the exported patients. Various casenode identifiers may be exported, if they are available in the system. Each patient is identified with a unique primary key. The participant referenced here is the person responsible for the patient inclusion into the given project (needed for payment).

A patient pseudonym or an additional identifier (=AID) also uniquely identifies a patient. This need not be exported though. The selection option for this depends on the project configuration.

Patients with the status set to "to-be-deleted" will never be exported. Patients with the status "delete pseudonym" will be exported if the option "all patients" have been chosen. Otherwise these patients will be omitted too.

The casenode table will be extended with the columns of the configurable randomization items as defined in the project. If the column names are not unique across the project the column names will be prefixed with the table name.

The variables for casenode are:

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	mnppid	Patient-ID	10	F10.0	Identifies each patient uniquely. This identifier is a unique number which each patient record receives automatically and can not be altered.
0	mnppsd	Patient pseudonym	\$20	A20	The random patient pseudonym. This identifier may not be exported.
0	mnpaid	Patient identifier	\$20	A20	An alternative patient identifier which may be entered when the patient is stored. This identifier may not be exported.
0	mnplabid	Patient identifier	\$20	A20	An alternative patient identifier which is given when the patient is created. This identifier may not be exported.
r	<i>mnprdm_no</i>	<i>Label of the randomization item + "no"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded or the centre-assignment of random numbers has been selected.
r	<i>mnprdm_gr</i>	<i>Label + "group"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded, the unblinded option has been selected for the export or some patients have been unblinded permanently due to an emergency.
2	mnpcnptnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user who entered the patient into the project. Investigators are exported as code lists and the identifier is the key of the code list.
1	mnpcntrid	Centre-ID	10	F10.0	The identifier of the centre. This information is not exported if centre data are not to be exported. Centres are exported as separate tables and this identifier is the primary key of that table.

	Variable	Label	SAS Length [Format]	SPSS Format	Description
m1	mnpcctrname	Centre name	\$100	A100	The name of the centre.
6	mnpcs0	Case status 0	2 [clcs_0x.]	F2.0	A status setting indicating that the patient record is not valid. [1 = 'not shown']
6	mnpcs1	Case status 1	2 [clcs_1x.]	F2.0	A status setting indicating that the patient record has been marked as being anonymized (no pseudonym). [1 = 'delete Pseudonym']
6	mnpcs2	Case status 2	2 [clcs_2x.]	F2.0	A status setting indicating that the patient record data is frozen and may not be changed. This status is not used at the moment; therefore it is not distinguished from the next. [1 = 'data frozen']
6	mnpcs3	Case status 3	2 [clcs_3x.]	F2.0	A status setting indicating that the patient record has been frozen automatically, set by rule [1 = 'data frozen']
6	mnpcs4	Case status 4	2 [clcs_4x.]	F2.0	A status setting indicating that the patient has deceased. [1 = 'deceased']
6	mnpcs5	Case status 5	2 [clcs_5x.]	F2.0	A status setting indicating that the patient data in this project is frozen and may not be changed. [1 = 'Project: data frozen']
6	mnpcs6	Case status 6	2 [clcs_6x.]	F2.0	A status setting indicating that the patient data in this project will be deleted. [1 = 'Project: to be deleted']
6	mnpcs7	Case status 7	2 [clcs_7x.]	F2.0	A status setting stating that no new visits may be added for this patient in this project. [1 = 'Project: closed visit plan']
3	mnvisstartdate	Entry date	DATE11.	DATE11	Date of patient entry into the project. Base for the calculation of the patients visit plan.

6.10 atcasenodes / atcn (Patient information history)

The audit trail tables of the patient visit plans are divided into two tables: 'atcn' and 'atcvp' which are exported with the "Audit trail" option. For casenodes the entry dates could be changed to adjust the base of the visit plan.

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	mnppid	Patient-ID	10	F10.0	Identifies each patient uniquely. This identifier is a unique number which each patient record receives automatically and can not be altered.
m0	mnppsd	Patient pseudonym	\$20	A20	The random patient pseudonym. This identifier may not be exported.
m0	mnpaid	Patient identifier	\$20	A20	An alternative patient identifier which may be entered when the patient is stored. This identifier may not be exported.
m0	mnplabid	Patient identifier	\$20	A20	An alternative patient identifier which is given when the patient is created. This identifier may not be exported.

	Variable	Label	SAS Length [Format]	SPSS Format	Description
mr	<i>mnp_rdm_no</i>	<i>Label of the randomization item + "no"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded or the centre-assignment of random numbers has been selected.
mr	<i>mnp_rdm_gr</i>	<i>Label + "group"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded, the unblinded option has been selected for the export or a patient has been unblinded permanently due to an emergency.
m2	<i>mnpcnptnid</i>	Participant-ID	10 [cltn.]	F10.0	The identifier of the user who entered the patient into the project. Investigators are exported as code lists and the identifier is the key of the code list.
m1	<i>mnpctrname</i>	Centre name	\$100	A100	The name of the centre.
m3	<i>mnpvisstartdate</i>	Entry date	DATE11.	DATE11	Date of patient entry into the project. Base for the calculation of the patients visit plan.
	<i>oldvisitstartdate</i>	Old entry date	DATE11.	DATE11	Former entry date before change of visit plan.
	<i>newvisitstartdate</i>	New entry date	DATE11.	DATE11	New date after the change of visit plan.
2	<i>mnpptnid</i>	Participant-ID	10 [cltn.]	F10.0	The identifier of the user who made the change of the entry date. Investigators are exported as code lists and the identifier is the key of the code list.
2	<i>mnpusid</i>	Patientuser-ID	10	F10.0	Patient ID if the patient has made the change instead of the participant, references the mnpid from the casenode table.
	<i>changedate</i>	Date of change	DATETIME20	DATETIME23.2	Timestamp of change.
	<i>changereason</i>	Reason for change	\$200	A200	Reason given by user.

6.11 **atcasevisitplans / atcvp** (Patient visit plan history)

The audit trail tables of the patients case visit plans are divided into two tables: 'atcn' and 'atcvp' which are exported with the "Audit trail" option. Patient visits could be changed in the planned visit date or - for unscheduled visits - in the visit type.

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	<i>mnpid</i>	Patient-ID	10	F10.0	Identifies each patient uniquely. This identifier is a unique number which each patient record receives automatically and can not be altered.

	Variable	Label	SAS Length [Format]	SPSS Format	Description
m0	mnppsd	Patient pseudonym	\$20	A20	The random patient pseudonym. This identifier may not be exported.
m0	mnpaid	Patient identifier	\$20	A20	An alternative patient identifier which may be entered when the patient is stored. This identifier may not be exported.
m0	mnplabid	Patient identifier	\$20	A20	An alternative patient identifier which is given when the patient is created. This identifier may not be exported.
mr	<i>mnp_rdm_no</i>	<i>Label of the randomization item + "no"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded or the centre-assignment of random numbers has been selected.
mr	<i>mnp_rdm_gr</i>	<i>Label + "group"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded, the unblinded option has been selected for the export or a patient has been unblinded permanently due to an emergency.
m2	mnpcnptnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user who entered the patient into the project. Investigators are exported as code lists and the identifier is the key of the code list.
m1	mnpcrname	Centre name	\$100	A100	The name of the centre.
m3	mnpvistartdate	Entry date	DATE11.	DATE11	Date of patient entry into the project. Base for the calculation of the patients visit plan.
	mnpcvpid	Patient visit-ID	10	F10.0	Unique identifier for the visit of a patient. If the visit has been deleted, this column is empty.
	oldmnpvispdt	old planned date of visit	DATE11.	DATE11	Former plan date before change of visit plan.
	newmnpvispdt	New planned date of visit	DATE11.	DATE11	New plan date after the change of visit plan. If the visit has been deleted, this column is empty.
	oldmnpvisid	Old visit-ID	10	F10.0	If the type of an unscheduled visit was changed, this is the former visit type.
	newmnpvisid	New visit-ID	10	F10.0	If the type of an unscheduled visit was changed, this is the new visit type. If the visit has

	Variable	Label	SAS Length [Format]	SPSS Format	Description
					been deleted, this column is empty.
	oldmnpvisno	Old patient-visit number	10	F10.0	The patient-visits are counted in the sequence of their creation, starting with 1. The counting is independently for the scheduled and unscheduled visits. Unscheduled visits are counted individually by type. If a visit type was changed, the absolute numbers and sequences have to be adjusted. The former number is stored here.
	newmnpvisno	New patient-visit number	10	F10.0	The patient-visits are counted in the sequence of their creation, starting with 1. The counting is independently for the scheduled and unscheduled visits. Unscheduled visits are counted individually by type. If a visit type was changed, the absolute numbers and sequences have to be adjusted. The new number is stored here. If the visit has been deleted, this column is empty.
2	mnpptrnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user who made the change of the visit. Investigators are exported as code lists and the identifier is the key of the code list.
2	mnppusid	Patientuser-ID	10	F10.0	Patient ID if the patient has made the change instead of the participant, references the mnppid from the casenode table.
	changedate	Date of change	DATETIME20.	DATETIME23.2	Timestamp of change.
	changereason	Reason for change	\$200	A200	Reason given by participant.

6.12 atadverseevents / atae (Patient's adverse event and follow-up history)

The audit trail tables of the patients adverse events and follow-ups are included into one table: 'atae' which is exported with the "Audit trail" option. Patient adverse events and follow-ups could be changed in the date or - for adverse events - in the adverse event number.

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	mnppid	Patient-ID	10	F10.0	Identifies each patient uniquely. This identifier is a unique number which each patient record receives automatically and can not be altered.
m0	mnppsd	Patient pseudonym	\$20	A20	The random patient pseudonym. This identifier may not be exported.

	Variable	Label	SAS Length [Format]	SPSS Format	Description
m0	mnpaid	Patient identifier	\$20	A20	An alternative patient identifier which may be entered when the patient is stored. This identifier may not be exported.
m0	mnplabid	Patient identifier	\$20	A20	An alternative patient identifier which is given when the patient is created. This identifier may not be exported.
mr	<i>mnprdm_no</i>	<i>Label of the randomization item + "no"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded or the centre-assignment of random numbers has been selected.
mr	<i>mnprdm_gr</i>	<i>Label + "group"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded, the unblinded option has been selected for the export or a patient has been unblinded permanently due to an emergency.
m2	mnpcnptnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user who entered the patient into the project. Investigators are exported as code lists and the identifier is the key of the code list.
m1	mnpcctrname	Centre name	\$100	A100	The name of the centre.
m3	mnpvistartdate	Entry date	DATE11.	DATE11	Date of patient entry into the project. Base for the calculation of the patients visit plan.
	mnpaeid	Adverse event-ID	10	F10.0	Unique identifier for the adverse event of a patient.
	mnpaefuid	Follow-up-ID	10	F10.0	Unique identifier of the follow-up of a patient. Only set for edited follow-ups.
	olddate	Old date	DATE11.	DATE11	Old date of adverse event or follow-up before editing. If the entry has been made for editing of adverse event (mnpaefuid is empty), this refers to the adverse event. If the entry has been made for editing of a follow-up

	Variable	Label	SAS Length [Format]	SPSS Format	Description
					(maneaefuid is set), this refers to the follow-up date.
	newdate	New date	DATE11.	DATE11	New date of adverse event or follow-up after editing. If the entry has been made for editing of adverse event (mnpaefuid is empty), this refers to the adverse event. If the entry has been made for editing of a follow-up (maneaefuid is set), this refers to the follow-up date.
	oldmnpaeno	Old patient adverse event number	10	F10.0	The patient-adverse events are counted in the sequence of their creation, starting with 1. If the chronological sequence had been change the sequence could have been adjusted. The former number is stored here.
	newmnpaeno	New patient adverse event number	10	F10.0	The patient-adverse events are counted in the sequence of their creation, starting with 1. If the chronological sequence had been change the sequence could have been adjusted. The new number is stored here.
2	mnpptnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user who made the change of the visit. Investigators are exported as code lists and the identifier is the key of the code list.
2	mnppusid	Patientuser-ID	10	F10.0	Patient ID if the patient has made the change instead of the participant, references the mnppid from the casenode table.
	changedate	Date of change	DATETIME20.	DATETIME23.2	Timestamp of change.
	changereason	Reason for change	\$200	A200	Reason given by editing user.

6.13 queries / qac (Queries)

This table is exported if it is chosen to export "queries and comments" option.

Queries and comments are annotations to the eCRFs. Each eCRF may have multiple queries and comments. One query can consist of many questions and answers. At last a query is resolved with a final remark. Resolved queries consist at least of one question, one answer and one final remark. Queries are placed upon single items in the form.

The variables for queries are:

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	mnppid	Patient-ID	10	F10.0	The unique patient identifier associating a query record to a patient record.
c	mnpctrid	Centre-ID	10	F10.0	The identifier of the centre (if the query was made on a centre-form).

	Variable	Label	SAS Length [Format]	SPSS Format	Description
m0	mnppsd	Patient pseudonym	\$20	A20	The random patient pseudonym. This identifier may not be exported.
m0	mnpaid	Patient identifier	\$20	A20	An alternative patient identifier which may be entered when the patient is stored. This identifier may not be exported.
m0	mnplabid	Patient identifier	\$20	A20	An alternative patient identifier which is given when the patient is created. This identifier may not be exported.
mr	<i>mntp_rdm_no</i>	<i>Label of the randomization item + "no"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded or the centre-assignment of random numbers has been selected.
mr	<i>mntp_rdm_gr</i>	<i>Label + "group"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded, the unblinded option has been selected for the export or a patient has been unblinded permanently due to an emergency.
m2	mnpcnptnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user who entered the patient into the project. Investigators are exported as code lists and the identifier is the key of the code list.
m1	mnpcctrname	Centre name	\$100	A100	The name of the centre.
m3	mntpvisstartdate	Entry date	DATE11.	DATE11	Date of patient entry into the project. Base for the calculation of the patients visit plan.
m3v	mntpvislabel	Visit label	\$50	A50	(Individual) visit label that is shown in the patient's form overview.
m3v	mntpvispdt	Planned date of visit	DATE11.	DATE11	The planned date of the visit. For a fixed visit this date is predefined by the visit plan. For flexible, free and unscheduled visits this date is entered during the creation of a new visit by the participant.
m3a	mntpaedate	Adverse Event date	DATETIME20.	DATETIME23.2	The date when the Adverse Event occurred.
m3a	mntpaeno	Adverse Event casenumber	10	F10.0	Individual number of the Adverse Event for the given casenode. This number is calculated during the creation of an Adverse Event, it does not necessarily represent the temporal order of events.
m3a	mntpaefuid	Adverse Event Follow-up-ID	10	F10.0	The ID of a follow-up to the Adverse Event.
m3a	mntpaefudt	Adverse Event Follow-up date	DATETIME20.	DATETIME23.2	The date when the patient data was collected for the follow-up.
m3i	mntpcrtdt	Document create date	DATETIME20.	DATETIME23.2	The date of the creation of this document.

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	mnpdocid	Document-ID	10	F10.0	Unique identifier of the eCRF to which this annotation has been added. As queries could be added on normal items or item in subforms, this is either the mnpdocid from the outer form or the mnpsubdocid from the inner form.
	ffid	Item-ID	10	F10.0	Identifier for the item, foreign key to table "items".
	ffcolname	DB column name	\$32	A32	Column name of the item.
5	hidden	hidden in DataCapture	2 [clhd.]	F2.0	A status setting indicating that this query is hidden in the DataCapture because either item, question, form or visit is hidden. [0 = 'no' 1 = 'yes']
	qacdate	Date of entry	DATETIME20.	DATETIME23.2	The date when the annotation was edited.
	mnpqueryid	Query-ID	10	F10.0	Unique identifier of a query. This field indicates which answer belongs to which question.
t	querytype	Query Type (Manual or Automatic)	\$1	A1	The type indicates if the query is the result of an automatically check (via discrepancies) or entered directly into the form. [A = 'Automatic' M = 'Manual']
	querystatus	Query Status (Calculated Status)	2 [clqa.]	F2.0	The result status of the actual sequence of queries and answers (= the status of the last query-entry). If the query is based on an automatic check (type="A"), then the final resolve could be marked for a new check. The last option is only available if the setup includes the discrepancies handling (DTM). [0 = 'no entry' 1 = 'Query' 2 = 'Answer' 4 = 'Resolved' 8 = 'Resolved and check again']
	qacstatus	QAC Status (type of query-entry)	2 [clqa.]	F2.0	The status of the single query entry. The type is the same as the result status of the whole query (see above).
2	mnpptnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user. Investigators are exported as code lists and the identifier is the key of the code list.
	qaccontent	Content	\$1000	A1000	The content of the annotation.

6.14 **comments / cts** (Comments)

This table is exported if the "queries and comments" option has been selected.

Comments are annotations to the eCRFs. Each eCRF may have multiple comments. The comments are single, unrelated remarks to single items.

The variables for Comments are:

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	mnppid	Patient-ID	10	F10.0	The unique patient identifier associating a comment record to a patient record.
c	mnpcctrid	Centre-ID	10	F10.0	The identifier of the centre (if the comment was made on a centre-form).
m0	mnppsd	Patient pseudonym	\$20	A20	The random patient pseudonym. This identifier may not be exported.
m0	mnpaid	Patient identifier	\$20	A20	An alternative patient identifier which may be entered when the patient is stored. This identifier may not be exported.
m0	mnplabid	Patient identifier	\$20	A20	An alternative patient identifier which is given when the patient is created. This identifier may not be exported.
mr	<i>mntp_rdm_no</i>	<i>Label of the randomization item + "no"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded or the centre-assignment of random numbers has been selected.
mr	<i>mntp_rdm_gr</i>	<i>Label + "group"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded, the unblinded option has been selected for the export or a patient has been unblinded permanently due to an emergency.
m2	mnpcnptnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user who entered the patient into the project. Investigators are exported as code lists and the identifier is the key of the code list.
m1	mnpcctrname	Centre name	\$100	A100	The name of the centre.
m3	mntpvisstartdate	Entry date	DATE11.	DATE11	Date of patient entry into the project. Base for the calculation of the patients visit plan.
m3v	mntpvislabel	Visit label	\$50	A50	(Individual) visit label that is shown in the patient's form overview.
m3v	mntpvispdt	Planned date of visit	DATE11.	DATE11	The planned date of the visit. For a fixed visit this date is predefined by the visit plan. For flexible, free and unscheduled visits this date is entered during the creation of a new visit by the participant.
m3a	mntpaedate	Adverse Event date	DATETIME20.	DATETIME23.2	The date when the Adverse Event occurred.
m3a	mntpaeno	Adverse Event casenumber	10	F10.0	Individual number of the Adverse Event for the given casenode. This number is calculated during the creation of an Adverse Event, it does not necessarily represent the

	Variable	Label	SAS Length [Format]	SPSS Format	Description
					temporal order of events.
m3a	mnpaefuid	Adverse Event Follow-up-ID	10	F10.0	The ID of a follow-up to the Adverse Event.
m3a	mnpaefudt	Adverse Event Follow-up date	DATETIME20.	DATETIME23.2	The date when the patient data was collected for the follow-up.
m3i	mnpcrtdt	Document create date	DATETIME20.	DATETIME23.2	The date of the creation of this document.
	mnpdoid	Document-ID	10	F10.0	Unique identifier of the eCRF to which this annotation has been added. As comments could be added on normal items or item in subforms, this is either the mnpdoid from the outer form or the mnpsubdoid from the inner form.
	ffid	Item-ID	10	F10.0	Identifier for the item, foreign key to table "items".
	ffcolname	DB column name	\$32	A32	Column name of the item.
5	hidden	hidden in DataCapture	2 [clhd.]	F2.0	A status setting indicating that this comment is hidden in the DataCapture because either item, question, form or visit is hidden. [0 = 'no' 1 = 'yes']
	qacdate	Date of entry	DATETIME20.	DATETIME23.2	The date when the annotation was edited.
	mnpcmentid	Comment-ID	10	F10.0	Unique identifier of a Comment.
2	mnppnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user. Investigators are exported as code lists and the identifier is the key of the code list.
	qaccontent	Content	\$1000	A1000	The content of the annotation.

6.15 **sdv / sdv** (Source Data Verification)

This table is exported when the selected project has this function configured and the corresponding export option was chosen. For every item there could be an entry in this table stating the state of SDV. If there is no entry, the item has the default status "not done". If the value of an SDV for an item or form has changed, the old values will be transferred in to the SDV audit trail table (see down).

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	mnppid	Patient-ID	10	F10.0	The unique patient identifier associating a comment record to a patient record.
c	mnpcrtrid	Centre-ID	10	F10.0	The identifier of the centre (if the SDV was performed on a centre-form).
m0	mnppsd	Patient pseudonym	\$20	A20	The random patient pseudonym. This identifier may not be exported.
m0	mnpaid	Patient identifier	\$20	A20	An alternative patient identifier which may be entered when the patient is stored. This identifier may not be exported.
m0	mnplabid	Patient identifier	\$20	A20	An alternative patient identifier which is given when the patient is created. This identifier may not be exported.
mr	<i>mnprdm_no</i>	<i>Label of the</i>	\$100	A100	Randomization similar to the form table

	Variable	Label	SAS Length [Format]	SPSS Format	Description
		<i>randomization item + "no"</i>			with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded or the centre-assignment of random numbers has been selected.
mr	<i>mnp_rdm_gr</i>	Label + "group"	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded, the unblinded option has been selected for the export or a patient has been unblinded permanently due to an emergency.
m2	mnpncptnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user who entered the patient into the project. Investigators are exported as code lists and the identifier is the key of the code list.
m1	mnpctrname	Centre name	\$100	A100	The name of the centre.
m3	mnpvisstartdate	Entry date	DATE11.	DATE11	Date of patient entry into the project. Base for the calculation of the patients visit plan.
m3v	mnpvislabel	Visit label	\$50	A50	(Individual) visit label that is shown in the patient's form overview.
m3v	mnpvispdt	Planned date of visit	DATE11.	DATE11	The planned date of the visit. For a fixed visit this date is predefined by the visit plan. For flexible, free and unscheduled visits this date is entered during the creation of a new visit by the participant.
m3a	mnpaedate	Adverse Event date	DATETIME20.	DATETIME23.2	The date when the Adverse Event occurred.
m3a	mnpaeno	Adverse Event casenumber	10	F10.0	Individual number of the Adverse Event for the given casenode. This number is calculated during the creation of an Adverse Event, it does not necessarily represent the temporal order of events.
m3a	mnpaefuid	Adverse Event Follow-up-ID	10	F10.0	The ID of a follow-up to the Adverse Event.
m3a	mnpaefudt	Adverse Event Follow-up date	DATETIME20.	DATETIME23.2	The date when the patient data was collected for the follow-up.
m3i	mnpctrtdt	Document create date	DATETIME20.	DATETIME23.2	The date of the creation of this document.
	mnpdocid	Document-ID	10	F10.0	Unique identifier of the eCRF on which the SDV has been performed. As SDV could be done on normal items or item in subforms, this is either the mnpdocid from the outer form or the mnpsubdocid from the inner form.
	ffid	Item-ID	10	F10.0	Identifier for the item, foreign key to table "items".
	ffcolname	DB column name	\$32	A32	Column name of the item.

	Variable	Label	SAS Length [Format]	SPSS Format	Description
5	hidden	hidden in DataCapture	2 [clhd.]	F2.0	A status setting indicating that this query is hidden in the DataCapture because either item, question, form or visit is hidden. [0 = 'no' 1 = 'yes']
	sdvdate	Date of entry	DATETIME20	DATETIME23.2	The date when the SDV was performed.
	mnpfssdv	Status SDV	2 [clfssdv.]	F2.0	Status of the referenced item. [1 = 'not done' 2 = 'not necessary' 4 = 'not possible' 8 = 'deferred' 16 = 'in progress' 32 = 'verified' 64 = 'verified with errors']
2	mnpptnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user. Investigators are exported as code lists and the identifier is the key of the code list.

6.16 **atsdv / atsdv** (Source Data Verification audit trail)

This table is exported when the selected project has this function configured and the SDV and audit trail export option was chosen. For every item there could be an entry in this table stating the former state of SDV. If there is no entry, the item has the default status "not done".

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	mnpid	Patient-ID	10	F10.0	The unique patient identifier associating a comment record to a patient record.
c	mnpctrld	Centre-ID	10	F10.0	The identifier of the centre (if the SDV was performed on a centre-form).
m0	mnpssd	Patient pseudonym	\$20	A20	The random patient pseudonym. This identifier may not be exported.
m0	mnpaid	Patient identifier	\$20	A20	An alternative patient identifier which may be entered when the patient is stored. This identifier may not be exported.
m0	mnpalbid	Patient identifier	\$20	A20	An alternative patient identifier which is given when the patient is created. This identifier may not be exported.
mr	mnp_rdm_no	Label of the randomization item + "no"	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded or the centre-assignment of random numbers has been selected.
mr	mnp_rdm_gr	Label + "group"	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded, the unblinded option has been selected for the export or a patient has been

	Variable	Label	SAS Length [Format]	SPSS Format	Description
					unblinded permanently due to an emergency.
m2	mnpcptnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user who entered the patient into the project. Investigators are exported as code lists and the identifier is the key of the code list.
m1	mnpctrname	Centre name	\$100	A100	The name of the centre.
m3	mnpvisstartdate	Entry date	DATE11.	DATE11	Date of patient entry into the project. Base for the calculation of the patients visit plan.
m3v	mnpvislabel	Visit label	\$50	A50	(Individual) visit label that is shown in the patient's form overview.
m3v	mnpvispdt	Planned date of visit	DATE11.	DATE11	The planned date of the visit. For a fixed visit this date is predefined by the visit plan. For flexible, free and unscheduled visits this date is entered during the creation of a new visit by the participant.
m3a	mnpaedate	Adverse Event date	DATETIME20.	DATETIME23.2	The date when the Adverse Event occurred.
m3a	mnpaeno	Adverse Event casenumber	10	F10.0	Individual number of the Adverse Event for the given casenode. This number is calculated during the creation of an Adverse Event, it does not necessarily represent the temporal order of events.
m3a	mnpaefuid	Adverse Event Follow-up-ID	10	F10.0	The ID of a follow-up to the Adverse Event.
m3a	mnpaefudt	Adverse Event Follow-up date	DATETIME20.	DATETIME23.2	The date when the patient data was collected for the follow-up.
m3i	mnpctrtdt	Document create date	DATETIME20.	DATETIME23.2	The date of the creation of this document.
	mnpatdocid	ATDocument-ID	10	F10.0	Unique identifier of the audit trail eCRF on which the SDV has been performed. As SDV could be done on normal items or item in subforms, this is either the mnpdocid from the outer form or the mnpsubdocid from the inner form.
	ffid	Item-ID	10	F10.0	Identifier for the item, foreign key to table "items".
	ffcolname	DB column name	\$32	A32	Column name of the item.
5	hidden	hidden in DataCapture	2 [clhd.]	F2.0	A status setting indicating that this query is hidden in the DataCapture because either item, question, form or visit is hidden. [0 = 'no' 1 = 'yes']
	sdvdate	Date of entry	DATETIME20	DATETIME23.2	The date when the SDV was performed.
	mnpfssdv	Status SDV	2 [clfssdv.]	F2.0	Status of the referenced item. [1 = 'not done' 2 = 'not necessary' 4 = 'not possible']

	Variable	Label	SAS Length [Format]	SPSS Format	Description
					8 = 'deferred' 16 = 'in progress' 32 = 'verified' 64 = 'verified with errors']
2	mnpptnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user. This information is not exported if investigator data are not to be exported. Investigators are exported as code lists and the identifier is the key of the code list.

6.17 **miv / miv** (Missing Values)

This table is exported when the selected project has this function configured and the corresponding export option was chosen. For every item there could be an entry in this table stating the state of Missing Values. If there is no entry, the item has the default status "Value exists". If the value of an MV for an item has changed, the old values will be transferred in to the MV audit trail table (see down).

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	mnppid	Patient-ID	10	F10.0	The unique patient identifier associating a comment record to a patient record.
c	mnpcntrid	Centre-ID	10	F10.0	The identifier of the centre (if the MV was performed on a centre-form).
m0	mnppsd	Patient pseudonym	\$20	A20	The random patient pseudonym. This identifier may not be exported.
m0	mnpaid	Patient identifier	\$20	A20	An alternative patient identifier which may be entered when the patient is stored. This identifier may not be exported.
m0	mnplabid	Patient identifier	\$20	A20	An alternative patient identifier which is given when the patient is created. This identifier may not be exported.
mr	<i>mnprdm_no</i>	<i>Label of the randomization item + "no"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded or the centre-assignment of random numbers has been selected.
mr	<i>mnprdm_gr</i>	<i>Label + "group"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded, the unblinded option has been selected for the export or a patient has been unblinded permanently due to an emergency.
m2	mnpcnptnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user who entered the patient into the project. Investigators are exported as code lists and the identifier is the key of the code list.

	Variable	Label	SAS Length [Format]	SPSS Format	Description
m1	mnpctrname	Centre name	\$100	A100	The name of the centre.
m3	mnpvisstartdate	Entry date	DATE11.	DATE11	Date of patient entry into the project. Base for the calculation of the patients visit plan.
m3v	mnpvislabel	Visit label	\$50	A50	(Individual) visit label that is shown in the patient's form overview.
m3v	mnpvispdt	Planned date of visit	DATE11.	DATE11	The planned date of the visit. For a fixed visit this date is predefined by the visit plan. For flexible, free and unscheduled visits this date is entered during the creation of a new visit by the participant.
m3a	mnpaedate	Adverse Event date	DATETIME20.	DATETIME23.2	The date when the Adverse Event occurred.
m3a	mnpaeno	Adverse Event casenumber	10	F10.0	Individual number of the Adverse Event for the given casenode. This number is calculated during the creation of an Adverse Event, it does not necessarily represent the temporal order of events.
m3a	mnpaefuid	Adverse Event Follow-up-ID	10	F10.0	The ID of a follow-up to the Adverse Event.
m3a	mnpaefudt	Adverse Event Follow-up date	DATETIME20.	DATETIME23.2	The date when the patient data was collected for the follow-up.
m3i	mnpcrtdt	Document create date	DATETIME20.	DATETIME23.2	The date of the creation of this document.
	mnpdocid	Document-ID	10	F10.0	Unique identifier of the eCRF on which the MV has been set. As MV could be done on normal items or item in subforms, this is either the mnpdocid from the outer form or the mnpsubdocid from the inner form.
	ffid	Item-ID	10	F10.0	Identifier for the item, foreign key to table "items".
	ffcolname	DB column name	\$32	A32	Column name of the item.
5	hidden	hidden in DataCapture	2 [clhd.]	F2.0	A status setting indicating that this query is hidden in the DataCapture because either item, question, form or visit is hidden. [0 = 'no' 1 = 'yes']
	editdate	Date of entry	DATETIME20	DATETIME23.2	The date when the MV was performed.
	mivstatus	Status MV	2 [clmiv.]	F2.0	Status of the referenced item, label depends on project configuration. [2 = 'Value not collected' 3 = 'Other reason for missing value' 4 = 'Value not collected due to rule']
	mivstatustext	Other reason for MV	\$250	A250	Other reason for missing value (freetext entry of user). May only be exported if project configured to use

	Variable	Label	SAS Length [Format]	SPSS Format	Description
					this MV status.
2	mnppntid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user. Investigators are exported as code lists and the identifier is the key of the code list.
2	mnppusid	Patientuser-ID	10	F10.0	10

6.18 **atmiv / atmiv** (Missing Values audit trail)

This table is exported when the selected project has this function configured and the MV and audit trail export option was chosen. For every item there could be an entry in this table stating the former state of MV. If there is no entry, the item has the default status "Value exists".

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	mnppid	Patient-ID	10	F10.0	The unique patient identifier associating a comment record to a patient record.
c	mnpcntrid	Centre-ID	10	F10.0	The identifier of the centre (if the MV was performed on a centre-form).
m0	mnppsd	Patient pseudonym	\$20	A20	The random patient pseudonym. This identifier may not be exported.
m0	mnpaid	Patient identifier	\$20	A20	An alternative patient identifier which may be entered when the patient is stored. This identifier may not be exported.
m0	mnplabid	Patient identifier	\$20	A20	An alternative patient identifier which is given when the patient is created. This identifier may not be exported.
mr	<i>mnprdm_no</i>	<i>Label of the randomization item + "no"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded or the centre-assignment of random numbers has been selected.
mr	<i>mnprdm_gr</i>	<i>Label + "group"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded, the unblinded option has been selected for the export or a patient has been unblinded permanently due to an emergency.
m2	mnpcnptnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user who entered the patient into the project. Investigators are exported as code lists and the identifier is the key of the code list.
m1	mnpcntrname	Centre name	\$100	A100	The name of the centre.
m3	mnppvisstartdate	Entry date	DATE11.	DATE11	Date of patient entry into the project. Base for the calculation of the patients visit plan.
m3v	mnppvislabel	Visit label	\$50	A50	(Individual) visit label that is shown in the patient's form overview.
m3v	mnppvispdt	Planned date	DATE11.	DATE11	The planned date of the visit. For a fixed

	Variable	Label	SAS Length [Format]	SPSS Format	Description
		of visit			visit this date is predefined by the visit plan. For flexible, free and unscheduled visits this date is entered during the creation of a new visit by the participant.
m3a	mnpaedate	Adverse Event date	DATETIME20.	DATETIME23.2	The date when the Adverse Event occurred.
m3a	mnpaeno	Adverse Event casenumber	10	F10.0	Individual number of the Adverse Event for the given casenode. This number is calculated during the creation of an Adverse Event, it does not necessarily represent the temporal order of events.
m3a	mnpaefuid	Adverse Event Follow-up-ID	10	F10.0	The ID of a follow-up to the Adverse Event.
m3a	mnpaefudt	Adverse Event Follow-up date	DATETIME20.	DATETIME23.2	The date when the patient data was collected for the follow-up.
m3i	mnpctrtdt	Document create date	DATETIME20.	DATETIME23.2	The date of the creation of this document.
	mnpatdocid	ATDocument-ID	10	F10.0	Unique identifier of the audit trail eCRF on which the SDV has been performed. As SDV could be done on normal items or item in subforms, this is either the mnpdocid from the outer form or the mnpsubdocid from the inner form.
	ffid	Item-ID	10	F10.0	Identifier for the item, foreign key to table "items".
	ffcolname	DB column name	\$32	A32	Column name of the item.
5	hidden	hidden in DataCapture	2 [clhd.]	F2.0	A status setting indicating that this query is hidden in the DataCapture because either item, question, form or visit is hidden. [0 = 'no' 1 = 'yes']
	editdate	Date of entry	DATETIME20	DATETIME23.2	The date when the MV was performed.
	mivstatus	Status MV	2 [clmiv.]	F2.0	Status of the referenced item, label depends on project configuration. [2 = 'Value not collected' 3 = 'Other reason for missing value' 4 = 'Value not collected due to rule']
	mivstatustext	Other reason for MV	\$250	A250	Other reason for missing value (freetext entry of user). May only be exported if project configured to use this MV status.
2	mnpptnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user. Investigators are exported as code lists and the identifier is the key of the code list.
2	mnppusid	Patientuser-ID	10	F10.0	10

6.19 mnp...: eCRF Data

The eCRF tables have names following the naming convention for short and long names described above. The audit records are stored in separate tables, and these have the same name as the table along with a constant prefix 'at'. The audit tables have the same structure as the data tables, with an additional new primary key. The original document is referenced by the original primary key.

The variable eCRFs have fixed and varying schema. Each eCRF table has the same fixed variables. The varying variables are eCRF dependent. The labels of the varying schema are taken from the form definition as made in the FormBuilder. If the item label is set, this is used directly. If no item label is set, the question label is used instead. If this is not set either, the unique label for search of the question is used, which must be set at least. If the item is the number part of a unit group, the standard unit is appended in brackets to the label.

Four types of eCRF record sets exist:

1. Data belonging to the casenode, independent of a visit. These eCRFs just have a reference to the patient casenode.
2. Data collected during patient visits. These eCRFs contain visit details. Each visit is identified by a visit-id. All records of one patient in the same visit have the same visit-id. For each patient the visits are numbered according creation sequence.
3. Data of Adverse Events and Serious Adverse Events. These eCRFs contain details of the Adverse Event and Follow-up. For each patient the adverse events are numbered according creation sequence.
4. Data of image forms could be created without study plan and related to either patient directly or every single visit or adverse event follow-up. These forms depend on corresponding templates in the project setup and are therefore not necessarily included into every study.

Some of the standard variables depend on the selected options for export. These are commented in the descriptions of the variables. Only a few variables depend on the overall project configuration as made in the FormBuilder or on the general setup of secuTrial®. These variables are explicitly stressed in the descriptions below. (The order of description is approximately the order of export.)

Some eCRF variables are only exported for special types of forms. These variables are marked by numbers explained below.

	Variable	Label	SAS Length [Format]	SPSS Format	Description
p	mnppid	Patient-ID	10	F10.0	The unique patient identifier associating an eCRF record to a patient record.
c	mnpcrid	Centre-ID	10	F10.0	The identifier of the centre (if this is a centre-form table).
pm0	mnppsd	Patient pseudonym	\$20	A20	The random patient pseudonym. This identifier may not be exported.
pm0	mnpaid	Patient identifier	\$20	A20	An alternative patient identifier which may be entered when the patient is stored. This identifier may not be exported.
pm0	mnplabid	Patient identifier	\$20	A20	An alternative patient identifier which is given when the patient is created. This identifier may not be exported.
pmr	<i>mnt_rdm_no</i>	<i>Label of the randomization item + "no"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded or the centre-assignment of random numbers has been selected.
pmr	<i>mnt_rdm_gr</i>	<i>Label + "group"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded, the unblinded option has been selected for the export or a patient

	Variable	Label	SAS Length [Format]	SPSS Format	Description
					has been unblinded permanently due to an emergency.
pm2	mnpncptnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user who entered the patient into the project. Investigators are exported as code lists and the identifier is the key of the code list.
m1	mnpctrname	Centre name	\$100	A100	The name of the centre.
pm3	mnpvisstartdate	Entry date	DATE11.	DATE11	Date of patient entry into the project. Base for the calculation of the patients visit plan.
	mnpdocid	Document-ID	10	F10.0	Each eCRF document record has a unique document identifier.
	ddeduplicatedid	Document-ID of the duplicate document for DDE	10	F10.0	Document-ID of the duplicate document for DDE (only set if this is the original document). This column is only exported, if the project configuration includes the DDE function.
	dderealdid	Document-ID of the real document for DDE	10	F10.0	Document-ID of the real document for DDE (only set if this is the duplicate document). This column is only exported if the project configuration includes the DDE function.
2	mnpplastedit	Date of last edit	DATETIME20.	DATETIME23.2	Date when record was last edited (=saved).
2	mnpptnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user who (last) saved the form. Investigators are exported as code lists and the identifier is the key of the code list.
2	mnpusid	Patientuser-ID	10	F10.0	Patient ID if the patient has made the change instead of the participant, references the mnppid from the casenode table. This column is only exported if the project configuration includes the PSD function.
p3v	mnpvisid	Visit-ID	10	F10.0	Identifier of the visit to which the eCRF belongs. This is the identifier for the common variables of the case visit plan.
3v	mnpvcpid	Patient visit-ID	10	F10.0	Unique identifier for each patient visit.
pm3v	mnpvislabel	Visit label	\$50	A50	(Individual) visit label that is shown in the patient's form overview.
p3v	mnpvisno	Patient visit number	10	F10.0	Individual number of visit for the given casenode. This number is calculated during the creation of the visit, it does not necessarily reflect the temporal sequence of visits. Scheduled and unscheduled visits are counted independently. Unscheduled visits are counted separate for each type.
p3v	mnpvgrno	Patient visit group number	10	F10.0	Individual number of repeating of group if the current visit is included in a (repeated) visit group.
p3v	mnpvispdt	Planned date of visit	DATE11.	DATE11	The planned date of the visit. For a fixed visit this date is predefined by the visit plan. For flexible, free and

	Variable	Label	SAS Length [Format]	SPSS Format	Description
					unscheduled visits this date is entered during the creation of a new visit by the participant.
p3v	mnpvisfdt	Date of first data entry in visit	DATETIME20.	DATETIME23.2	The date of first data entry. Normally this should be the real date of visit.
p3a	mnpaeid	Adverse Event-ID	10	F10.0	Unique identifier of an Adverse Event.
p3a	mnpaedate	Adverse Event date	DATETIME20.	DATETIME23.2	The date when the Adverse Event occurred.
p3a	mnpaeno	Adverse Event casenumber	10	F10.0	Individual number of the Adverse Event for the given casenode. This number is calculated during the creation of an Adverse Event, it does not necessarily represent the temporal order of events.
p3a	mnpaefuid	Adverse Event Follow-up-ID	10	F10.0	The ID of a follow-up to the Adverse Event.
p3a	mnpaefudt	Adverse Event Follow-up date	DATETIME20.	DATETIME23.2	The date when the patient data was collected for the follow-up.
p3i	mnpctrtdt	Document create date	DATETIME20.	DATETIME23.2	The date of the creation of this document.
p3i	mnpctrpt	Document creator (participant)	10 [cltn.]	F10.0	The user who creates this document. This information is not exported if investigator data are not to be exported. Investigators are exported as code lists and the identifier is the key of the code list.
p3i	mnpctrpusid	Document creator (patientuser)	10	F10.0	The patientuser who creates this document. This is the Patient ID if the patient has made the change instead of the participant, references the mnppid from the casenode table. This column is only exported if the project configuration includes the PSD function.
7	mnpfs0	Form status (Review A)	2 [clfs_0x.]	F2.0	A status stating that the record has been reviewed with review level 1. [1 = 'medical reviewed(A) ']
7	mnpfs1	Form status (Review B)	2 [clfs_1x.]	F2.0	A status stating that the record has been reviewed with review level 2. [1 = 'data reviewed(B) ']
7	mnpfs2	Form status (Freeze)	2 [clfs_2x.]	F2.0	A status stating that the record is manually frozen and data may no longer be altered. [1 = 'manually frozen']
7	mnpfs3	Form status (System-Freeze)	2 [clfs_3x.]	F2.0	A status stating that the record is frozen by system and data may no longer be altered. [1 = 'rule based frozen']
7	mnpfcs0	Form completion status	2 [clfs_0x.]	F2.0	A status indicating that the completion status of a record. [0 = 'empty' 2 = 'partially completed' 4 = 'completed']

	Variable	Label	SAS Length [Format]	SPSS Format	Description
7	mnpfcs1	Validation status (error)	2 [clfs_1x.]	F2.0	A status stating that validation errors are stored in the record. [1 = 'with error']
7	mnpfcs2	Validation status (warning)	2 [clfs_2x.]	F2.0	A status indicating that confirmation warnings are stored in the record. [1 = 'with warning']
7	mnpfcs3	Data entry complete status	2 [clfs_3x.]	F2.0	A status indicating the data entry on this record is completed. Further changes are only possible if queries are made. This status is only exported, if the project configuration includes the DEC workflow.
7	mnpfsqa	Form status Queries	2 [clfsqa.]	F2.0	A status stating if any query or answered query is set on this record. If the status is set to 'Query' there is at least one open query on this record. If the status is set to 'Answer' than all existing queries on this record has been answered. [0 = '' 1 = 'with open query' 2 = 'with answered query' 4 = 'all queries resolved']
7	mnpfsct	Form status Comments	2 [clct.]	F2.0	A status stating if any comment has been made on this record. [1 = 'with comment']
7	mnpfssdv	Form status SDV	2 [clfsdv.]	F2.0	A status stating the progress of source data verification. This status is only exported, if the project configuration includes the SDV function. [1 = 'not done' 2 = 'not necessary' 4 = 'not possible' 8 = 'deferred' 16 = 'in progress' 32 = 'verified' 64 = 'verified with errors']
7	mnpfsdde	Form status DDE	2 [clfsdde.]	F2.0	A status describing the progress of the double data entry (DDE). This status is only exported, if the project configuration includes the DDE function. [0 = 'DDE comparison finished' 1 = 'entry in progress' 2 = 'entry completed' 3 = 'ignore' (duplicate)]
5	mnpfhide	hidden in DataCapture	2 [clhd.]	F2.0	A status setting indicating that this document is hidden in the DataCapture because either form or visit is hidden, or form is currently not shown in visit. This column is only exported if the project includes any hidden element. [0 = 'no' 1 = 'yes']

	Variable	Label	SAS Length [Format]	SPSS Format	Description
4	siguser	Signature user	\$200	A200	Textual representation of the user: TNTITEL+TNVORNAME + TNNACHNAME (of table PARTICIPANT). Only for validation purposes.
4	sigtext	Signature text	\$30	A30	This is the textual description of the action leading to data storing. It is the same signature text that the user was presented during the signature process. It has been stored textually in the database as presented.
2	sigstatus	Signature status	\$2	F2.0	Numerical description of the action leading to data storing. This flag is always set, independent of any necessary e-signature. Meaning of values: [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 (only with SDV) 10 = revoke review A 11 = query resolved 12 = data entry complete (only DEC) 13 = modify data (only DEC) 14 = manual freeze 15 = data import 16 = revoke entry complete (only DEC) 17 = Query withdrawn 19 = DDE entry 20 = DDE entry completed 21 = DDE entry reopened 22 = DDE comparison finished 23 = DDE entry corrected 24 = revalidate]
4	sigvalid	Signature validity	\$10	A10	Validity of signature. This is only exported if chosen by option. [valid invalid not signed]
4	sigversion	Signature algorithm version	2	F2.0	Numerical type of signature algorithm version. [0 = signature made before 3.1 1 = signature made since 3.1 2 = signature made since 4.0]
2	sigreason	Reason for modification	\$200	A200	Manually entered reason for modification of data after setting the "data entry complete" status. Required only for this action. This column is only exported if the project configuration includes the DEC workflow.
2	mnpvsno	Version number	10	F10.0	Version number of the project with which the eCRF was stored (will only be set in productive area).
2	mnpvsbl	Version label	\$30	A30	Version label of the project with which

	Variable	Label	SAS Length [Format]	SPSS Format	Description
					the eCRF was stored (in the setup area this is a timestamp of the last project setup editing).

6.20 atmnp...: Audit Trail eCRF

The tables of the audit trail are similar to the normal eCRF tables (see documentation above). Additionally, they have an own primary key "mnpatdocid". The reference to the original document is made via the "mnpdocid".

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	mnpdocid	Document-ID	10	F10.0	The original eCRF document record unique document identifier.
	mnpatdocid	ATDocument-ID	10	F10.0	The unique identifier for the audit trail document itself.

6.21 emnp...: Sub-Documents

The screenshot shows the 'Concomitant Medication' sub-form in the secuTrial system. The header displays patient information: Date: 09.04.2010 - 19:00 (CEST), Clinical Investigator: Dipl.biол Susanne Schneider, Patient: Pa-ID agz877, Add-ID sus123, Lab-ID 222ucw, Visite 1: 08.03.2010 (CET), Project: Basisregister (09.04.2010 - 18:47:26 (CEST)), Form family: Begleitmedikation, Centre: Berlin, Form: Concomitant Medication. The breadcrumb trail is: Welcome > Patient agz877 > Concomitant Medication. The main form area is titled 'Concomitant Medication' and contains a table for 'Medication 1' and 'Medication 2'. Each row has columns for 'Registered Trademark', 'Dose (eg. 500)', 'Unit (eg. mg)', 'Start Date', 'End Date', 'Continuing', and 'Comment'. Below the table are buttons for 'Cancel', 'Save', 'Save + close entry', and a 'Check data' checkbox. At the bottom, a status bar repeats the patient and visit information.

Fig. 7: Example of a repetition group with a subform. In this case there are no other items in the outer form.

eCRFs may contain repetition fields, which may have several values in one eCRF. An example is an eCRF with *medication*. A patient often takes more than one type of medication, and these may be recorded using repetition fields. A repetition itself may contain many fields, in the medication example it might be the *Registered trademark*, the *Dose* and *Continuing* it is taken. These data are stored and exported in separate tables, which contain a reference to the main eCRF.

Sub-document tables have the naming convention that all table names start with an 'e' for extended. If short names are to be used, the prefix is omitted from the table name.

	Variable	Label	SAS Length [Format]	SPSS Format	Description
p	mnppid	Patient-ID	10	F10.0	The unique patient identifier associating an eCRF record to a patient record.
c	mnpctrid	Centre-ID	10	F10.0	The identifier of the centre (if this is a centre-subform table).
pm0	mnppsd	Patient pseudonym	\$20	A20	The random patient pseudonym. This identifier may not be exported.
pm0	mnpaid	Patient identifier	\$20	A20	An alternative patient identifier which may be entered when the

	Variable	Label	SAS Length [Format]	SPSS Format	Description
					patient is stored. This identifier may not be exported.
pm0	mnplabid	Patient identifier	\$20	A20	An alternative patient identifier which is given when the patient is created. This identifier may not be exported.
pmr	mnprdm_no	Label of the randomization item + "no"	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded or the centre-assignment of random numbers has been selected.
pmr	mnprdm_gr	Label + "group"	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded, the unblinded option has been selected for the export or a patient has been unblinded permanently due to an emergency.
pm2	mnpcptnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user who entered the patient into the project. Investigators are exported as code lists and the identifier is the key of the code list.
pcm1	mnpctrname	Centre name	\$100	A100	The name of the centre.
pm3	mnpvisstartdate	Entry date	DATE11.	DATE11	Date of patient entry into the project. Base for the calculation of the patients visit plan.
pm3v	mnpvislabel	Visit label	\$50	A50	(Individual) visit label that is shown in the patient's form overview.
pm3v	mnpvispdt	Planned date of visit	DATE11.	DATE11	The planned date of the visit. For a fixed visit this date is predefined by the visit plan. For flexible, free and unscheduled visits this date is entered during the creation of a new visit by the participant.
pm3a	mnpaedate	Adverse Event date	DATETIME20.	DATETIME23.2	The date when the Adverse Event occurred.
pm3a	mnpaeno	Adverse Event casenumber	10	F10.0	Individual number of the Adverse Event for the given casenode. This number is calculated during the creation of an Adverse Event, it does not necessarily represent the temporal order of events.
pm3a	mnpaefuid	Adverse Event Follow-up-ID	10	F10.0	The ID of a follow-up to the Adverse Event.
pm3a	mnpaefudt	Adverse Event Follow-up date	DATETIME20.	DATETIME23.2	The date when the patient data was collected for the follow-up.
pm3i	mnpcrtdt	Document create date	DATETIME20.	DATETIME23.2	The date of the creation of this document.
	mnpdocid	Parent document-ID	10	F10.0	The reference to the main (parent) document.

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	mnpsubdocid	Subdocument-ID	10	F10.0	Unique identifier of the subdocument.
	fgid	Question-ID of Repetition	10	F10.0	Unique identifier of the repetition-question of the parent document.
	position	Position in Repetition	10	F10.0	Position in the repetition of the parent document starting with "0".

6.22 **atemnp...**: Audit Trail Sub-Documents

The audit trail tables of the sub-forms are exported in a similar way (see documentation above). In contrast to the audit trail of the normal eCRFs, the sub-documents do not reference the original sub-document but instead reference the outer audit trail document. This is necessary because if a repetition was deleted prior to saving, there would be no original sub-document to refer to. Therefore the audit trail of the sub-documents contains a new primary key and a new reference to the (audit trail) parent document.

	Variable	Label	SAS Length [Format]	SPSS Format	Description
p	mnppid	Patient-ID	10	F10.0	The unique patient identifier associating an eCRF record to a patient record.
c	mnpcrid	Centre-ID	10	F10.0	The identifier of the centre (if this is a centre-subform table).
	mnpatdocid	Parent ATDocument-ID	10	F10.0	The identifier of the main (parent) audit trail document.
	mnpsubdocid	ATSubdocument-ID	10	F10.0	The unique identifier for the audit trail subdocument itself.
	fgid	Question-ID of Repetition	10	F10.0	Unique identifier of the repetition-question of the parent (at)document.
	position	Position in Repetition	10	F10.0	Position in the repetition of the parent (at)document starting with "0".

6.23 **images / img** (Images)

If there are any images included into the eCRF data either in normal or special image forms, the image references in the eCRF data are resolved in this separate image table. If the binary images are included into the export, the corresponding file name and file status columns are appended to this table (see below).

The binary data are included in an "patientimages" folder inside the zip.

	Variable	Label	SAS Length [Format]	SPSS Format	Description
	mnppid	Patient-ID	10	F10.0	The unique patient identifier associating an eCRF record to a patient record.
c	mnpcrid	Centre-ID	10	F10.0	The identifier of the centre (if the image was uploaded in a centre-form).
m0	mnppsd	Patient pseudonym	\$20	A20	The random patient pseudonym. This identifier may not be exported.
m0	mnpaid	Patient identifier	\$20	A20	An alternative patient identifier which may be entered when the patient is stored. This identifier may not be exported.
m0	mnplabid	Patient	\$20	A20	An alternative patient identifier

	Variable	Label	SAS Length [Format]	SPSS Format	Description
		identifier			which is given when the patient is created. This identifier may not be exported.
mr	<i>mnp_rdm_no</i>	<i>Label of the randomization item + "no"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded or the centre-assignment of random numbers has been selected.
mr	<i>mnp_rdm_gr</i>	<i>Label + "group"</i>	\$100	A100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded, the unblinded option has been selected for the export or a patient has been unblinded permanently due to an emergency.
m2	mnpcnptnid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user who entered the patient into the project. Investigators are exported as code lists and the identifier is the key of the code list.
m1	mnpctname	Centre name	\$100	A100	The name of the centre.
m3	mnpvisstartdate	Entry date	DATE11.	DATE11	Date of patient entry into the project. Base for the calculation of the patients visit plan.
m3v	mnpvislabel	Visit label	\$50	A50	(Individual) visit label that is shown in the patient's form overview.
m3v	mnpvispdt	Planned date of visit	DATE11.	DATE11	The planned date of the visit. For a fixed visit this date is predefined by the visit plan. For flexible, free and unscheduled visits this date is entered during the creation of a new visit by the participant.
m3a	mnpaedate	Adverse Event date	DATETIME20.	DATETIME23.2	The date when the Adverse Event occurred.
m3a	mnpaeno	Adverse Event casenumber	10	F10.0	Individual number of the Adverse Event for the given casenode. This number is calculated during the creation of an Adverse Event, it does not necessarily represent the temporal order of events.
m3a	mnpaefuid	Adverse Event Follow-up-ID	10	F10.0	The ID of a follow-up to the Adverse Event.
m3a	mnpaefudt	Adverse Event Follow-up date	DATETIME20.	DATETIME23.2	The date when the patient data was collected for the follow-up.
m3i	mnpcrtdt	Document create date	DATETIME20.	DATETIME23.2	The date of the creation of this document.
	mnpimgid	Image-ID	10	F10.0	The unique identifier for the image. This ID is referenced in the eCRF tables.
	uploadedfilename	Uploaded file	\$500	A500	This is the original name from the client before the upload. As this is

	Variable	Label	SAS Length [Format]	SPSS Format	Description
					not necessarily unique all files are renamed on the server and for export.
	contenttype	Content type	\$40	A40	Type of file as given by the uploading browser.
	imagesize	Image size (bytes)	22	F22.0	File size measured in bytes.
	uploaddate	Date of upload	DATETIME20.	DATETIME23.2	Timestamp of upload.
2	mnppntid	Participant-ID	10 [cltn.]	F10.0	The identifier of the user who uploaded the image. This information is not exported if investigator data are not to be exported. Investigators are exported as code lists and the identifier is the key of the code list.
2	mnppusid	Patientuser-ID	10	F10.0	Patient ID if the patient has made the upload instead of the participant, references the mnppid from the casenode table. This column is only exported if the project configuration includes the PSD function.
8	originalfile	Original file name	\$100	A100	The file name of the uploaded file on the server resp. in the export.
8	originalstatus	Status of original file	\$15	A15	The status of the included original file. If the file is nonexistent this is an error for the original file as this should always exist. [valid invalid nonexistent]
8	webfile	Web file name	\$100	A100	For the display on the eCRF in the system a reduced web image could have been created during upload if possible for the uploaded file type.
8	webstatus	Status of web file	\$15	A15	The status of the included web file. As the creation of a web image depends on file type a nonexistent web image could be valid. Possible values: [valid invalid nonexistent]
8	thumbnailfile	Thumbnail file name	\$100	A100	For the display on report of patient matrix in the system a small thumbnail image could have been created during the upload if possible for the uploaded file type.
8	thumbnailstatus	Status of thumbnail file	\$15	A15	The status of the included thumbnail file. As the creation of a thumbnail image depends on file type a nonexistent web image could be valid. Possible values: [valid

	Variable	Label	SAS Length [Format]	SPSS Format	Description
					invalid nonexistent]

6.24 data

This table is exported for the rectangular export format.

	Variable	Label	SAS Length [Format]	SPSS Format	CSV /TXT Leng th	Description
Patient						
	mnppid	Patient-ID	10	F10.0	10	Identifies each patient uniquely. This identifier is a unique number which each patient record receives automatically and can not be altered.
0	mnppsd	Patient pseudonym	\$20	A20	20	The random patient pseudonym. This identifier need not be exported.
0	mnpaid	Patient identifier	\$20	A20	20	An alternative patient identifier which may be entered when the patient is stored. This identifier need not be exported.
0	mnplabid	Patient identifier	\$20	A20	20	An alternative patient identifier
3	mnpptrnid	Participant-ID	10 [cltn.]	F10.0	150	The identifier of the user who entered the patient into the project. Investigators are exported as code lists and the identifier is the key of the code list. CSV/TXT: full name of the participant,
Centre						
1	mnpcrid	Centre-ID	10	F10.0	200	The identifier of the centre. CSV/TXT: name of the centre.
1	mnpcid	Country name	\$100	A100	100	The identifier of the country CSV/TXT: The name of the country.
Patient status						
6	mnpcs0	Case status 0	2 [clcs_0x.]	F2.0	30	A status setting indicating that the patient record is not shown in the DataCapture. This status can be set by rule "anonymize patient" or in the AdminTool. [1 = 'not shown']
6	mnpcs1	Case status 1	2 [clcs_1x.]	F2.0	30	A status setting indicating that the patient record has been marked as being anonymized (no pseudonym). [1 = 'deleted Pseudonym']
6	mnpcs3	Case status 3	2 [clcs_3x.]	F2.0	30	A status setting indicating that the patient record has been frozen. This status can be set by rule 'freeze patient' or in the AdminTool.

	Variable	Label	SAS Length [Format]	SPSS Format	CSV /TXT Leng th	Description
						[1 = 'data frozen']
6	mnpcs4	Case status 4	2 [clcs_4x.]	F2.0	30	A status setting indicating that the patient has deceased. This status can be set by rule 'patient deceased' or in the AdminTool. [1 = 'deceased']
6	mnpcs5	Case status 5	2 [clcs_5x.]	F2.0	30	A status setting indicating that the patient data in this project is frozen and may not be changed. This status can be set by rule 'freeze casenode' or in the AdminTool. [1 = 'Project: data frozen]
6	mnpcs7	Case status 7	2 [clcs_7x.]	F2.0	30	A status setting stating that no new visits may be added for this patient in this project. This status can be set by rule 'freeze following forms' or in the AdminTool. [1 = 'Project: closed visit plan']
3	mnpvisstartdate	Entry date	DATE11	DATE11	10	Date of patient entry into the project. Base for the calculation of the patients visit plan.
r	random	Label of the randomization item	\$100	A100	100	Randomization similar to the form table with the randomization button item. There may be multiple columns of this type. The columns includes either the randomization number or the randomization group depending on blinding of the project and choosen export option. This column(s) is(are) only exported if the configurable randomization is used in the project.
r	mnp_rdm_gr	Label + "group"	\$100	A100	100	Randomization similar to the form table with the randomization button item. Depending on project setup there may be multiple columns of this type. This column is exported if the randomization is blinded, the unblinded option has been selected for the export or a patient has been unblinded permanently due to an emergency.
Form data						
Scheme of column names for visit forms (example)						
	v12_1_mnpxytable_mnpdocid	Visit: Visit repetition: Table:				listed by primary key, here with visitid = 21 1 mnp0table ('mnp' + project scheme + user entered value), for SAS format the tablesnames are replaced by a number to avoid too long column names. The

Variable	Label	SAS Length [Format]	SPSS Format	CSV /TXT Leng th	Description
		Column: Optional for sub forms:			replacement is documented in the <i>formnumbers</i> table. column name as defined per user (eCRF item) or meta data (see table descriptions) ID of Repetitiongroup-question and number of repetition
Scheme of column names for casenode forms (example)					
c_mnpxytable_mnpdocid		Table: entered value) Column: Optional for sub forms:			mnptp0table ('mnp' + project scheme + user entered value) column name as defined per user (eCRF item) or meta data ID of Repetitiongroup-question and number of repetition
Scheme of column names for adverse event forms (example)					
a1_3_mnpxytable_mnpdocid		Adverse event number: Repetition/Followup: Table: Column: Optional for sub forms:			counted by existance per patient, here = 1 counted by existance per patient, here = 3 mnptp0table ('mnp' + project scheme + user entered value) column name as defined per user (eCRF item) or meta data ID of Repetitiongroup-question and number of repetition
Scheme of column names for image forms (example)					
i5_mnpxytable_mnpdocid		Image form: Table: Column: Optional for sub forms:			repetition: 5 mnptp0table ('mnp' + project scheme + user entered value) column name as defined per user (eCRF item) or meta data ID of Repetitiongroup-question and number of repetition
<i>The following columns are repeated for each form.</i>					
mnpdocid	Document-ID	10	F10.0	10	Each eCRF document record has a unique document identifier.
Document edit					
2 mnplastedit	Date of last edit	DATETIME20	DATETIME23.2	18	Date when record was last edited (=saved).
2 mnpptnid	Participant-ID	10 [cltn.]	F10.0	150	The identifier of the user who created the form. Investigators are exported as code lists and the identifier is the key of the code list. CSV/TXT: Full name of participant
2 mnppusid	Patientuser-ID	10	F10.0	10	Patient ID if the patient has made the change instead of the participant, references the mnppid from the casenode table. If set this is the same ID as the current patient. This column is only exported if the project configuration includes the PSD function.
2 sigstatus	Signature status	\$2	F2.0	2	Numerical description of the action leading to data storing.

	Variable	Label	SAS Length [Format]	SPSS Format	CSV /TXT Length	Description
						<p>This flag is always set, independent of any necessary e-signature. Meaning of values:</p> <p>[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 (only with SDV) 10 = revoke review A 11 = query resolved 12 = data entry complete (only DEC) 13 = modify data (only DEC) 14 = manual freeze 15 = data import 16 = revoke entry complete (only DEC) 17 = Query withdrawn 19 = DDE entry 20 = DDE entry completed 21 = DDE entry reopened 22 = DDE comparison finished 23 = DDE entry corrected] 24 = REVALIDATE</p>
	2 sigreason	Reason for modification	\$200	A200	200	Manually entered reason for modification of data after setting the "data entry complete" status. Required only for this action. This column is only exported if the project configuration includes the DEC workflow.
	2 0mnpvsno	Version number	10	F10.0	10	Version number of project (will only be set in productive area).
	2 mnpvslbl	Version label	\$30	A30	30	Version label of project (will only be set in productive area).
Signature validation						
	4 siguser	Signature user	\$200	A200	200	Textual representation of the user: TNTITEL+TNVORNAME + TNNACHNAME (of table PARTICIPANT). Only for validation purposes.
	4 sigtext	Signature text	\$30	A30	30	This is the textual description of the action leading to data storing. It is the same signature text that the user was presented during the signature process.
	4 sigvalid	Signature validity	\$10	A10	10	Validity of signature. This is only exported if chosen by option. [valid invalid not signed]

	Variable	Label	SAS Length [Format]	SPSS Format	CSV /TXT Leng th	Description
4	sigversion	Signature algorithm version	2	F2.0	2	Numerical type of signature algorithm version. [0 = signature made before 3.1 1 = signature made since 3.1 2 = signature made since 4.0]
Structure						
3v	mnpvcpid	Patient visit-ID	10	F10.0	10	Unique identifier for each patient visit.
3v	mnpvisno	Visit number	10	F10.0	10	Individual number of visit for the given casenode. This number is calculated during the creation of the visit, it does not necessarily reflect the temporal sequence of visits. Scheduled and unscheduled visits are counted independently. Unscheduled visits are counted separate for each type.
3v	mnpvispdt	Planned date of visit	DATE9	DATE11	10	The planned date of the visit. For a fixed visit this date is predefined by the visit plan. For flexible, free and unscheduled visits this date is entered during the creation of a new visit by the participant.
3v	mnpvisfdt	Date of first data entry in visit	DATETIME20	DATETIME23.2	18	The date of first data entry. Normally this should be the real date of visit.
3a	mnpaeid	Adverse Event-ID	10	F10.0	10	Unique identifier of an Adverse Event.
3a	mnpaedeate	Adverse Event date	DATETIME20	DATETIME23.2	18	The date when the Adverse Event occurred.
3a	mnpaeno	Adverse Event casenumber	10	F10.0	10	Individual number of the Adverse Event for the given casenode. This number is calculated during the creation of an Adverse Event, it does not necessarily represent the temporal order of events.
3a	mnpaefuid	Adverse Event Follow-up-ID	10	F10.0	10	The ID of a follow-up to the Adverse Event.
3a	mnpaefudt	Adverse Event Follow-up date	DATETIME20	DATETIME23.2	18	The date when the patient data was collected for the follow-up.
3i	mnpctrtdt	Document create date	DATETIME20	DATETIME23.2	18	The date of the creation of this document.
3i	mnpctrpt	Document creator (participant)	10 [cltn.]	F10.0	150	The user who creates this document. This information is not exported if investigator data are not to be exported. Investigators are exported as code lists and the identifier is the key of the code list. CSV/TXT: full name of participant.

	Variable	Label	SAS Length [Format]	SPSS Format	CSV /TXT Length	Description
	3i mnpctrpusid	Document creator (patientuser)	10	F10.0	10	The patientuser who creates this document. This is the current Patient ID if the patient has made the change instead of the participant. This column is only exported if the project configuration includes the PSD function.
Form status						
	7 mnpfs0	Form status (Review A)	2 [clfs_0x.]	F2.0	30	A status stating that the record has been reviewed with review level 1. [1 = 'medical reviewed(A) ']
	7 mnpfs1	Form status (Review B)	2 [clfs_1x.]	F2.0	30	A status stating that the record has been reviewed with review level 2. [1 = 'data reviewed(B) ']
	7 mnpfs2	Form status (Freeze)	2 [clfs_2x.]	F2.0	30	A status stating that the record is manually frozen and data may no longer be altered. [1 = 'manually frozen']
	7 mnpfs3	Form status (System-Freeze)	2 [clfs_3x.]	F2.0	30	A status stating that the record is frozen by system and data may no longer be altered. [1 = 'rule based frozen']
	7 mnpfcs0	Form completion status	2 [clfs_0x.]	F2.0	30	A status indicating that the completion status of a record. [0 = 'empty' 2 = 'partially completed' 4 = 'completed']
	7 mnpfcs1	Validation status (error)	2 [clfs_1x.]	F2.0	30	A status stating that validation errors are stored in the record. [1 = 'with error']
	7 mnpfcs2	Validation status (warning)	2 [clfs_2x.]	F2.0	30	A status indicating that confirmation warnings are stored in the record. [1 = 'with warning']
	7 mnpfcs3	Data entry complete status	2 [clfs_3x.]	F2.0	30	A status indicating the data entry on this record is completed. Further changes are only possible if queries are made. This status is only exported, if the project configuration includes the DEC workflow.
	7 mnpfsqa	Form status Queries	2 [clfsqa.]	F2.0	30	A status stating if any query or answered query is set on this record. If the status is set to 'Query' there is at least one open query on this record. If the status is set to 'Answer' than all existing queries on this record has been answered. [0 = '' 1 = 'with open query' 2 = 'with answered query' 4 = 'all queries

Variable	Label	SAS Length [Format]	SPSS Format	CSV /TXT Length	Description
					resolved']
7 mnpfsct	Form status Comments	2 [clct.]	F2.0	30	A status stating if any comment has been made on this record. [1 = 'with comment']
7 mnpfssdv	Form status SDV	2 [clfssdv.]	F2.0	30	A status stating the progress of source data verification. This status is only exported if the project configuration includes the SDV function. [1 = 'not done' 2 = 'not necessary' 4 = 'not possible' 8 = 'deferred' 16 = 'in progress' 32 = 'verified' 64 = 'verified with errors']
7 mnpfsdde	Form status DDE	2 [clfsdde.]	F2.0	30	A status describing the progress of the double data entry (DDE). This status is only exported if the project configuration includes the DDE function. [0 = 'DDE comparison finished' 1 = 'entry in progress' 2 = 'entry completed' 3 = 'ignore' (duplicate)]
5 mnphide	Hidden in DataCapture	\$2	F2.0	30	Status determines if the form was hidden explicitly. This status is only exported if the project configuration includes any hidden element.
Form content data according project definition					
According to the form definition the user defined items are listed for each form. Subforms are repeated as often as the maximal number for each export. The item repetitions are marked by appending repetition indices.					

NOTE: It is not possible to export form data of visit forms not shown in any visit with the rectangular export format!

6.25 formnumbers

This table is only exported for the rectangular SAS format. Here the form table names in the column names are replaced by simple numbers in the sequence of occurrence in export. To map the numbers to the table names this information is given in a separate table.

Variable	Label	SAS Length/ Format	SPSS Format	Description
formid	Form-ID	10	F10.0	Identifier of the Form-Definition. This may not be the same ID as in the non-rectangular setup definition.
formtablename	DB table name	\$100	A100	Table name as given in the project setup definition.