#### secuTrialR - a walk through

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# Introduction

"If I had just five minutes to chop down a tree I would spend the first two and a half minutes sharpening my axe."

— An anonymous woodsman

This R package provides functions for handling data from the clinical data management system (CDMS) secuTrial. The most important components are related to reading data exports from secuTrial into R. In brief, the package aims to enable swift execution of repetitive tasks in order to allow spending more time on the unique aspects of a dataset. It is developed and maintained by the Swiss Clinical Trial Organisation (SCTO).

If you are still challenged by more basic operations in R we suggest reading Hands-On Programming with R, which serves as an excellent introduction to the basic concepts of R.

This vignette will teach you how to use the **secuTrialR** package and you will likely learn quite a bit about secuTrial exports in general along the way. Throughout the **secuTrialR** package and within this vignette we refer to patients, cases, subjects etc. enrolled in a secuTrial database as participants.

# Install

Please note that R versions  $\geq$  3.5 should be used to run secuTrialR.

#### Stable release from CRAN

install.packages("secuTrialR", dependencies = TRUE)

#### Development release from GitHub with devtools

For this you will need to have devtools installed. If you are working on Windows and would like to install with devtools you will likely need to install Rtools. Installing everything, including the dependencies, from scratch may take a while (20-30 minutes).

```
# install
devtools::install_github("SwissClinicalTrialOrganisation/secuTrialR")
# load silently
suppressMessages(library(secuTrialR))
# show secuTrialR version
packageVersion("secuTrialR")
#> [1] '1.3.3'
```

# The CTU05 dataset

Before we continue with the functionalities let's briefly talk about the test data which is delivered as a part of the package. We refer to it as the CTU05 (clinical trial unit project 05) data. This dataset has been fabricated for demonstration purposes only and is not real clinical data. Principally it is made up of eight forms. These are called "surgeries", "baseline", "outcome", "treatment", "allmedi", "studyterminat", "ae" and "sae". You will see these names again later when the data has been read into R. The project setup includes most data types implementable in secuTrial. It is, however, not exhaustive. Since the data is delivered with the installation of the secuTrialR package we can point to it via the system.file() function.

If you work on your own datasets you can specify a path as a regular character string without using system.file().

# secuTrial export options

Prior to reading your data into R you need to export it with the secuTrial ExportSearchTool. We suggest exporting non-rectangular, zipped, English data with reference values stored in a separate table including Add-IDs, centre information, structure information, form status, project setup, without duplicated meta data and without form data of hidden fields. Furthermore, it is important to use "CSV format"/"CSV format for MS Excel" and suggested to select UTF-8 encoding. Most of these options are truly optional and reading your data should work even with differences from the above specifications.

A description of how data can be exported from secuTrial can be found here. This description includes screenshots of the export options configuration interface.

# Reading a secuTrial data export into R

There is one principle function to read your data (i.e. read\_secuTrial()). Below you can see it in action with the CTU05 dataset.

```
ctu05_data <- read_secuTrial(data_dir = ctu05_data_location)
#> Read export successfully.
#> The following export options deviate from the suggested specifications:
#> Data from hidden fields is part of the export.
```

If the "Read export successfully." message appears your data was correctly read. In this example you are also warned that hidden data fields are in the export which is a deviation from the suggested export option configuration.

# The secuTrialdata object

If you inspect the class() of ctu05\_data you will find that it is a secuTrialdata object.

```
class(ctu05_data)
#> [1] "secuTrialdata"
```

Really this is only a list containing all the information from your secuTrial export.

```
typeof(ctu05_data)
#> [1] "list"
```

## The data tables in the secuTrialdata object

We have implemented a custom variation of the print() function for secuTrialdata objects.

pri	nt(ctu05_data)					
#>	secuTrial data in	nporte	ed fro	om:		
#>	C:/Users/haynes/A	AppDat	a/Loo	cal/Ten	np/RtmpEbZjcQ/Rinst83	c016fa36b3/secuTrialR/extdata/sT_exports/exp_o
#>	table	nrow	ncol	meta	original_name	
#>	vp	4	13	TRUE	vp.csv	
#>	vpfs	8	2	TRUE	vpfs.csv	
#>	fs	8	8	TRUE	fs.csv	
#>	qs	29	8	TRUE	qs.csv	
#>	is	85	9	TRUE	is.csv	
#>	ctr	3	3	TRUE	ctr.csv	
#>	cn	11	16	TRUE	cn. csv	
#>	atcn	0	9	TRUE	atcn.csv	
#>	atcvp	0	16	TRUE	atcvp.csv	
#>	qac	0	15	TRUE	qac.csv	
#>	cts	0	12	TRUE	cts.csv	
#>	miv	0	10	TRUE	miv.csv	
#>	atmiv	0	14	FALSE	atmiv.csv	
#>	baseline	17	107	FALSE	baseline.csv	
#>	at baseline	1	79	FALSE	at baseline.cs v	
#>	outcome	13	48	FALSE	outcome.csv	
#>	atoutcome	5	47	FALSE	atoutcome.csv	
#>	treatment	11	44	FALSE	treatment.csv	
#>	attreatment	0	45	FALSE	attreatment.csv	
#>	allmedi	17	47	FALSE	allmedi.csv	
#>	atallmedi	2	47	FALSE	atallmedi.csv	
#>	study terminat	10	41	FALSE	study terminat.csv	
#>	atstudy terminat	1	39	FALSE	atstudyterminat.csv	
#>	ae	1	66	FALSE	ae.csv	
#>	atae	0	58	FALSE	atae.csv	
#>	sae	2	64	FALSE	sae.csv	
#>	atsae	0	57	FALSE	atsae.csv	
#>	esurgeries	18	11	FALSE	esurgeries.csv	
#>	atesurgeries	1	9	FALSE	atesurgeries.csv	
#>	cl	211	3	TRUE	cl.csv	
#>	atae1	0	20	FALSE	atae1.csv	

It shows you where the export archive of your secuTrialdata object is located, tells you which data tables (i.e. table) it contains, what the source files (i.e. original\_name) are and specifies each table's dimensions (i.e. ncol, nrow).

By now you have possibly realized that all the forms specified earlier (i.e. "surgeries", "baseline", "outcome", "treatment", "allmedi", "studyterminat", "ae" and "sae") are present, but also that there are many tables that do not correspond to the previously introduced forms.

The majority of the unfamiliar tables are tagged as TRUE in the meta column. This means that they are metadata tables. Their names and data structures are fixed in secuTrial exports. In the following we will briefly explain which information the most relevant meta tables contain.

- vp visitplan definition
- vpfs visitplan form linkage
- fs forms information
- qs questions
- is items i.e. variable definitions

- ctr centre information
- cn casenodes i.e. table of entered study participants
- cl information how the data in the variables is coded

Furthermore, there is a set of tables whose names start with "at". These are audit trail tables. They are only relevant if you need to investigate changes in the data over time. For example certain values may be corrected (i.e. changed) due to findings during monitoring visits at study centres. Last but not least you may have also realized that the "surgeries" table is called **esurgeries**. This is because it is a so-called repetition form. Repetition forms are labelled with a leading "e" and are implemented as subforms in other forms. In this case, **esurgeries** is a subform in **baseline** and the linkage is defined by the **mnpdocid** column in both tables. If this sounds cryptic to you we suggest you talk so someone who has implemented a database in secuTrial and let them explain it with a specific example. It is pretty straight forward when you look at a concrete implementation.

#### Accessing the tables and values

Since the secuTrialdata object is a list and the data tables within this list are data.frames you can simply access the tables using \$. Let's say you would like to have a look at the placebo to verum ratio in your treatment data or what types of other medication were entered in allmedi.

```
table(ctu05_data$treatment$rando_treatment)
#>
#> Placebo Verum
#> 8 3
table(ctu05_data$allmedi$med_product)
#>
#> Amoxicillin Doxycycline Importal
#> 2 1 3
```

## Data transformations

During the loading process, coded categorical data is transformed. For example the gender variable in the **baseline** form is categorical. The raw data is accessible via gender and the transformed version of the data is added during the reading process and becomes accessible via gender.factor. Thus, data is not overwritten but added with the .factor extension. If there are issues during factorization a warning() will inform you of this.

```
# raw gender data
ctu05_data$baseline$gender
#> [1] 1 NA NA 2 1 2 1 NA NA 1 2 NA NA 1 2 2 NA
#> attr(, "label")
#> [1] "Gender"
# transformed gender data
ctu05_data$baseline$gender.factor
#> [1] male
             <NA>
                     <NA>
                            female male female male
                                                        <NA>
                                                              <NA>
                                                                     male
#> [11] female <NA>
                     <NA>
                            male female female <NA>
#> attr(, "label")
#> [1] Gender
#> Levels: male female
```

# raw more meds
ctu05\_data\$allmedi\$no\_more\_meds
#> [1] 1 1 0 1 1 1 0 0 0 1 0 0 1 1 1 1 0

```
#> attr(,"label")
#> [1] "No further medication"
# transformed more meds
ctu05_data$allmedi$no_more_meds.factor
#> [1] yes yes no yes yes yes no no no yes no no yes yes yes no
#> attr(,"label")
#> [1] No further medication
#> Levels: no yes
```

Note that descriptive labels have also been automatically added to the data.

```
label(ctu05_data$allmedi$no_more_meds.factor)
#> [1] "No further medication"
label(ctu05_data$baseline$gender.factor)
#> [1] "Gender"
label(ctu05_data$esurgeries$surgery_organ.factor)
#> [1] "Organ"
```

Datetime data is also transformed and similarly to the factorization process the names are concatenated with .date or .datetime.

```
# raw
ctu05_data$baseline$visit_date
#> [1] 20190401 20190402 20190403 20190402 20190403 20190404 20190405 20190406
#> [9] 20190407 20190411 20190412 20190413 20190414 20190413 20190414 20190415
#> [17] 20180501
#> attr(, "label")
#> [1] "Date of visit"
# processed
ctu05_data$baseline$visit_date.date
#> [1] "2019-04-01" "2019-04-02" "2019-04-03" "2019-04-02" "2019-04-03"
#> [6] "2019-04-04" "2019-04-05" "2019-04-06" "2019-04-07" "2019-04-11"
#> [11] "2019-04-12" "2019-04-13" "2019-04-14" "2019-04-13" "2019-04-14"
#> [16] "2019-04-15" "2018-05-01"
# raw only head
head(ctu05_data$baseline$hiv_date)
#> [1] 201903052356
                                                        NA
                                                                      NA
                              NA
                                           NA
#> [6]
                 NA
# processed only head
head(ctu05_data$baseline$hiv_date.datetime)
#> [1] "2019-03-05 23:56:00 CET" NA
#> [3] NA
                                 NA
#> [5] NA
                                 NA
# classes
class(ctu05_data$baseline$visit_date)
#> [1] "integer"
```

```
class(ctu05_data$baseline$visit_date.date)
#> [1] "Date"
class(ctu05_data$baseline$hiv_date)
#> [1] "numeric"
class(ctu05_data$baseline$hiv_date.datetime)
```

#> [1] "POSIXct" "POSIXt"

Depending on the setup, incomplete dates can be valid entries in a secuTrial database. Thus they will also occasionally appear in your exports. The datetime conversion does not work in these cases and NAs are created. If this happens, **secuTrialR** will warn you accordingly and you should have a closer look into the affected datetime variables and whether you would like to perform so-called date imputation.

## **Export** options

The secuTrialdata object also contains information on the export options.

```
ctu05_data$export_options
#> secuTrial version: 6.5.1.5
#> Time of export on server: 13.05.2024 - 12:40:06 (CEST)
#> Project version: (20.06.2019 - 11:22:04 (CEST))
#> Exported with short names
#> File extension: csv
#> Enclosure: '\"'
#> Seperator: ','
#> 32 files exported
   including 13 metadata tables
#>
#> Reference values exported - factorize possible
#> Metadata tables:
#>
                 type exportname available
#>
               forms
                              fs
                                      TRUE
#>
                                      TRUE
           casenodes
                              cn
#>
             centres
                             ctr
                                      TRUE
#>
               items
                                      TRUE
                             is
#>
           questions
                              qs
                                      TRUE
#>
                             qac
                                      TRUE
             queries
#>
           visitplan
                                      TRUE
                             vp
#>
      visitplanforms
                            vpfs
                                      TRUE
#>
         at cas enodes
                            atcn
                                      TRUE
#>
   at case visit plans
                           atcvp
                                      TRUE
#>
            comments
                             cts
                                      TRUE
#>
                 miυ
                             miυ
                                      TRUE
#>
                  cl
                              cl
                                      TRUE
```

export\_options itself is a list. If you are interested in more information than is printed you can also access it. Let's assume you would like to know the project\_name and encoding.

```
ctu05_data$export_options$project_name
#> [1] "secuTrialR example CDMA"
```

```
ctu05_data$export_options$encoding
#> [1] "UTF-8"
```

Much more information is stored in the elements of export\_options. The names of the elements should be descriptive enough to infer the contents.

nam	es(ct	u05_data\$export_optic	ons)	
#>	[1]	"sep"	"quote"	"date_format"
#>	[4]	"datetime_format"	"date_format_meta"	"na.strings"
#>	[7]	"short_names"	"is_zip"	"is_rectangular"
#>	[10]	"audit_trail"	"column_names"	"lang_not_supported"
#>	[13]	"dict_items"	"refvals_separate"	"add_id"
#>	[16]	"lab_id"	"meta_names"	"meta_available"
#>	[19]	"duplicate_meta"	"all_files"	"data_files"
#>	[22]	"data_names"	"file_end"	"extension"
#>	[25]	"data_dir"	"secuTrial_version"	"project_version"
#>	[28]	"project_name"	"format_info"	"time_of_export"
#>	[31]	"encoding"	"form_status"	"centre_info"
#>	[34]	"hidden_fields"	"structure"	"proj_setup"
#>	[37]	"factorized"	"dated"	"labelled"

# Generic functions for secuTrialdata objects

Now that you understand the **secuTrialdata** object we will show you some generic functions you can use on objects of this class.

# Show the study participants

First off you may be interested in a table of participants.

get_p	articipa	ants(ctu05_data	a)	
#>	mnppid	mnpaid	mnpctrid	mnpctrname
<b>#&gt; 1</b>	1204	RPACK-CBE-001	462	Charité Berlin (RPACK)
#> 2	1205	RPACK-CBE-002	462	Charité Berlin (RPACK)
<b>#&gt;</b> 3	1206	RPACK-CBE-003	462	Charité Berlin (RPACK)
#> 4	1207	RPACK-CBE-004	462	Charité Berlin (RPACK)
#> 5	1208	RPACK-CBE-005	462	Charité Berlin (RPACK)
#> 6	1209	RPACK-INS-011	461	Inselspital Bern (RPACK)
#> 7	1210	RPACK-INS-012	461	Inselspital Bern (RPACK)
<b>#&gt;</b> 8	1211	RPACK-INS-013	461	Inselspital Bern (RPACK)
<b>#&gt;</b> 9	1212	RPACK-INS-014	461	Inselspital Bern (RPACK)
#> 10	) 1213	RPACK-INS-015	461	Inselspital Bern (RPACK)
#> 11	1214	RPACK-USB-123	441	Universitätsspital Basel (RPACK)

Please note that the mnpaid column in this table corresponds to the pat\_id column in other tables.

## Recruitment over time

You can extract information about participant recruitment per centre and year by applying annual\_recruitment() on a secuTrialdata object.

annua	al_recruitment(ctu05_data)	)				
#>		Center	Total	2018	2019	
#> 1		All	11	1	10	
#> 2	Charité Berlin	(RPACK)	5	0	5	
<b>#&gt;</b> 3	Inselspital Bern	(RPACK)	5	0	5	
#> 4	Universitätsspital Basel	(RPACK)	1	1	0	

Since the centre names often have a systematic addition (e.g. (RPACK)) we have enabled the option to remove certain parts of the centre descriptions via regular expressions (i.e. **rm\_regex** argument). In this case the regular expression removes trailing parentheses and everything they enclose.

annua	al_recruitment(ctu05_data,	rm_re	egex =	= "\\(	.*\\)\$")
#>	Center	Total	2018	2019	
#> 1	All	11	1	10	
#> 2	Charité Berlin	5	0	5	
#> 3	Inselspital Bern	5	0	5	
#> 4	Universitätsspital Basel	1	1	0	

It is also possible to plot the recruitment over time.

plot\_recruitment(ctu05\_data, cex = 1.2, rm\_regex = "\\(.\*\\)\$")

## **Recruitment over time**



Date of enrollment

# Visit plan visualization

secuTrialR can provide a depiction of the visit structure, although only where the visit plan is fixed. Black rectangles in the grid represent a form to be filled (x) during one of the visits (y).





# **Completeness of forms**

If you are not sure about how complete the data in your export is, it may be useful to get a quick overview of how well the forms have been filled. The below table shows both absolute and relative numbers for a few forms.

```
fss <- form_status_summary(ctu05_data)</pre>
tail(fss, n = 5)
#>
          form_name partly_filled completely_filled empty with_warnings
#> 7
                                 3
                                                   14
                                                          0
           baseline
                                                                         1
#> 8
            outcome
                                 1
                                                   12
                                                          0
                                                                         0
#> 9
                                 0
                                                    2
                                                          0
                                                                         0
                sae
#> 10 studyterminat
                                 0
                                                   10
                                                          0
                                                                         0
#> 11
          treatment
                                 0
                                                   11
                                                          0
                                                                         0
#>
      with\_errors\ partly\_filled.percent\ completely\_filled.percent\ empty.percent
#> 7
                0
                              0.17647059
                                                           0.8235294
                                                                                  0
#> 8
                0
                              0.07692308
                                                          0.9230769
                                                                                  0
#> 9
                              0.0000000
                                                          1.0000000
                                                                                  0
                0
#> 10
                0
                              0.0000000
                                                          1.0000000
                                                                                  0
#> 11
                0
                              0.0000000
                                                           1.0000000
                                                                                  0
#>
      with_warnings.percent with_errors.percent form_count
#> 7
         0.05882353
                                                0
                                                           17
```

#>	8	0.0000000	0	13
#>	9	0.0000000	0	2
#>	10	0.0000000	0	10
#>	11	0.0000000	0	11

Please note that a form is only complete if all required fields have been filled. Thus, a whole study may have 99% completeness on variable basis while showing 0% completeness on form basis. It is currently not technically possible to assess completeness on variable basis in a generic way. Hence, high completeness on form basis implies high completeness on variable basis but **NOT** vice versa.

If you would rather retrieve information on form completeness for each participant individually you can perform the following.

```
fsc <- form_status_counts(ctu05_data)</pre>
# show the top
head(fsc)
#>
            pat\_id form\_name completely\_filled partly\_filled empty with\_warnings
#> 1 RPACK-CBE-001 baseline
                                               3
                                                             0
                                                                    0
                                                                                  0
#> 2 RPACK-CBE-002 baseline
                                               1
                                                             0
                                                                    0
                                                                                  0
#> 3 RPACK-CBE-003 baseline
                                              1
                                                             0
                                                                    0
                                                                                  0
#> 4 RPACK-CBE-004
                    baseline
                                              1
                                                             0
                                                                    0
                                                                                  0
#> 5 RPACK-CBE-005 baseline
                                                             2
                                              1
                                                                    0
                                                                                  0
#> 6 RPACK-INS-011 baseline
                                               1
                                                             0
                                                                    0
                                                                                  0
#>
     with_errors
#> 1
               0
               0
#> 2
#> 3
               0
#> 4
               0
#> 5
               0
#> 6
               0
```

## Form linkage

Linkages amongst forms can be explored with the links\_secuTrial() function. This relies on the igraph package to create a network. It is possible to interact with the network, e.g. move nodes around in order to read the labels better. The R graphics device ID is returned to the console, but can be ignored. Forms are plotted in deep yellow, variables in light blue.

#### links\_secuTrial(ctu05\_data)

The output can not be shown within this vignette but you should give it a try. Please note that the linkage plot is likely most useful **without** the audit trail data in the export.

## Sampling random participants

During study monitoring it is common practice to check random participants from a study database. These participants should be retrieved in a reproducible fashion, which can be achieved by setting a so-called seed. The below function allows reproducible retrieval for a loaded secuTrial data export.

```
# randomly retrieve at least 25 percent of participants recorded after March 18th 2019
# from the centres "Inselspital Bern" and "Charité Berlin"
return_random_participants(ctu05_data,
                           percent = 0.25,
                           seed = 1337,
                           date = "2019-03-18",
                           centres = c("Inselspital Bern (RPACK)",
                                        "Charité Berlin (RPACK)"))
#> $participants
#>
            mnpaid
                                      centre mnpvisstartdate
#> 2 RPACK-INS-012 Inselspital Bern (RPACK)
                                                  2019-04-12
#> 4 RPACK-INS-014 Inselspital Bern (RPACK)
                                                  2019-04-14
#> 5 RPACK-CBE-005
                     Charité Berlin (RPACK)
                                                  2019-04-05
#> 3 RPACK-CBE-003
                     Charité Berlin (RPACK)
                                                  2019-04-03
#>
#> $rng_config
#> [1] "Mersenne-Twister" "Inversion"
                                              "Rejection"
```

Please note that earlier R versions may return different results because there is a different rng\_config (i.e. RNGkind()). For this reason we have added the rng\_config to the output.

## Retrieve score variables

secuTrial allows implementing calculated variables (i.e. scores). Data is not directly entered into these variables but rather calculated automatically. Scores are defined by a set of rules and use the data in other variables as basis. For example the age of a study participant at data entry can be calculated as the difference between the participant's birthday and the day of data entry.

It is advisable to recalculate or validate score variable data before data analysis. A rule of thumb: The more complex a score is and the more data from different forms is necessary for its calculation the more likely its value should be recalculated. The below function will allow you to detect which variables this concerns.

```
return_scores(ctu05_data)
#> name itemtype label
#> 1 age Years y (calculated only) Age
```

## Retrieve hidden variables

Sometimes, during a study, certain fields may be hidden because data should no longer be entered into them. If this is the case and the data of these fields is part of your export is likely good to know about it. In this case nothing is hidden.

```
return_hidden_items(ctu05_data)
#> [1] name itemtype label
#> <0 rows> (or 0-length row.names)
```

## Finding changes/differences in project setup implementations

In ongoing studies it is possible that changes to the secuTrial data entry interface (i.e. the electronic case report forms) are made. Sometimes these changes may call for adjustments in analysis code. It is considered good practice to run diff\_secuTrial() on the last export and the current export of a project to at least make yourself aware of potential changes in the setup. If there are differences, the results of this function should be interpreted as a first indicator since they may not cover all alterations. Information is returned on forms and variables. A detailed list of changes can be produced in the secuTrial FormBuilder with "Compare project setup".

For the below diff\_secuTrial() showcase we emulated a changed setup of CTU05 by copying the setup and importing it in the FormBuilder as a new secuTrial project (CTU06). From this, we created a data export (v1) and then made a few minor changes and exported again (v2). If this sounds confusing, never mind. CTU06 v1 is simply a copy of CTU05. CTU06 v2 is a slightly altered version of CTU06 v1.

```
ctu06_v1 <- read_secuTrial(system.file("extdata", "sT_exports", "change_tracking",</pre>
                                        "s export CSV-xls CTU06 version1.zip",
                                        package = "secuTrialR"))
#> Read export successfully.
#> The following export options deviate from the suggested specifications:
#> Data from hidden fields is part of the export.
#> Short names was not selected.
ctu06_v2 <- read_secuTrial(system.file("extdata", "sT_exports", "change_tracking",</pre>
                                        "s_export_CSV-xls_CTU06_version2.zip",
                                        package = "secuTrialR"))
#> Read export successfully.
#> The following export options deviate from the suggested specifications:
#> Data from hidden fields is part of the export.
diff secuTrial(ctu06 v1, ctu06 v2)
#> $new forms
#> [1] "mnpctu06anewform"
                                 "mnpctu06anothernewform"
#>
#> $new_variables
#> [1] "new item in fu"
                              "new_item_in_new_form"
#>
#> $removed_forms
#> character(0)
#>
#> $removed_variables
#> character(0)
```

As you can see ctu06\_v2 contains the two additional forms mnpctu06anewform and mnpctu06anothernewform and the two additional variables new\_item\_in\_fu and new\_item\_in\_new\_form.

# Conversion to SPSS, STATA, SAS

Given that you are working with R it is unlikely that you need such conversions for yourself. However, collaborators may ask for data which is readily importable into SPSS, STATA or SAS. For this you can use write\_secuTrial().

Since this has not been heavily tested or used there may be issues and you might prefer doing this manually with the **haven** package. One particular sticking point is the length of variable names - R is not restrictive in this respect, but other software can be. **secuTrialR** does not truncate names, prefering to leave this to the user, which can cause **write\_secuTrial()** to fail with an error.

```
# retrieve path to a temporary directory
tdir <- tempdir()
# write spss
write_secuTrial(ctu05_data, format = "sav", path = tdir)</pre>
```

## Subsetting secuTrialdata

In some cases it may be useful to subset your secuTrialdata object. For example if you have cohort data and would like to supply a subset of the data for a retrospective study. We have implemented this option with subset\_secuTrial(). It will truncate your secuTrialdata object and return a new secuTrialdata object which is a subset of the original data. It is possible to subset by including or excluding specific participant ids or centres.

```
# initialize some subset identifiers
participants <- c("RPACK-INS-011", "RPACK-INS-014", "RPACK-INS-015")</pre>
centres <- c("Inselspital Bern (RPACK)", "Universitätsspital Basel (RPACK)")</pre>
# exclude Bern and Basel
ctu05_data_berlin <- subset_secuTrial(ctu05_data, centre = centres, exclude = TRUE)
#> If you changed any labels in the secuTrialdata object manually these will be reset to their original
# exclude Berlin
ctu05_data_bern_basel <- subset_secuTrial(ctu05_data, centre = centres)</pre>
#> If you changed any labels in the secuTrialdata object manually these will be reset to their original
# keep only subset of participants
ctu05_data_pids <- subset_secuTrial(ctu05_data, participant = participants)</pre>
#> If you changed any labels in the secuTrialdata object manually these will be reset to their original
class(ctu05_data_berlin)
#> [1] "secuTrialdata"
class(ctu05_data_bern_basel)
#> [1] "secuTrialdata"
```

```
class(ctu05_data_pids)
#> [1] "secuTrialdata"
```

If you subset based on centres all traces of deleted centres will be removed. If you remove based on participant ids all traces of deleted participants will be removed.

```
# only Berlin remains
ctu05_data_berlin$ctr
#> mnpctrid
                        mnpctrname mnpcname
#> 1 462 Charité Berlin (RPACK)
                                        NA
# all centres remain even though all three participant ids are from Bern
ctu05_data_pids$ctr
#> mnpctrid
                                 mnpctrname mnpcname
                    Charité Berlin (RPACK)
#> 1
      462
                                                 NA
        461
                                                 NA
#> 2
                   Inselspital Bern (RPACK)
       441 Universitätsspital Basel (RPACK)
#> 3
                                                 NA
```

Since the truncated object's class remains unchanged (i.e. secuTrialdata) you can still use the generic functions on it. Let's say you would only like to look at the recruitment plot for Bern alone.

```
# keep only Bern
ctu05_data_bern <- subset_secuTrial(ctu05_data, centre = "Inselspital Bern (RPACK)")
#> If you changed any labels in the secuTrialdata object manually these will be reset to their original
```

# # plot plot\_recruitment(ctu05\_data\_bern)



## **Recruitment over time**

Date of enrollment

 $\ldots\,$  or Bern and Berlin.

plot\_recruitment(ctu05\_data\_bern\_berlin)

## **Recruitment over time**



# Building URLs to your secuTrial server

If you are creating reports in which you would like to directly link to specific pages of your secuTrial Data-Capture you can use build\_secuTrial\_url. If you are no expert regarding the secuTrial server architecture you would like to build links for, you should talk to the server admin or consult the build\_secuTrial\_url help page. They will be able to guide you regarding the information for the server, instance, customer and project parameters. The docid, however, is included in your export data in the non-meta data tables of the secuTrialdata object and can be found in the mnpdocid columns.

```
head(ctu05_data$treatment$mnpdocid)
#> [1] 181 193 200 205 213 224
head(ctu05_data$baseline$mnpdocid)
```

```
#> [1] 180 184 187 191 199 203
```

To demsonstrate build\_secuTrial\_url we will use imaginary data for the server, instance, customer and project parameters. The real counterparts on your server will likely look structurally similar.

## These are the links:

https://server.secutrial.com/apps/WebObjects/ST21-setup-DataCapture.woa/wa/choose?customer=TE S&projectid=7036&docid=180

 $\label{eq:https://server.secutrial.com/apps/WebObjects/ST21-setup-DataCapture.woa/wa/choose?customer=TES&projectid=7036&docid=184$ 

https://server.secutrial.com/apps/WebObjects/ST21-setup-DataCapture.woa/wa/choose?customer=TEinstein the setup and the setup a

S&projectid=7036&docid=187

Of course they are dead ends but maybe you can use them to make out the arguments for your server.

# The as.data.frame function

This vignette has been working with the secuTrialdata object, which is of type list. For some users, working with a list can be tiresome so secuTrialR provides an as.data.frame() method to save the data.frames in the secuTrialdata object to an environment of your choice.

As an example, we will create an environment called **env** and check that it's empty before running as.data.frame()...

```
env <- new.env()
ls(env)
#> character(0)
# add files to env
as.data.frame(ctu05_data, envir = env)
... and afterwards.
ls(env)
```

```
[1] "ae"
                           "allmedi"
                                               "atae"
#>
                                                                  "atae1"
    [5] "atallmedi"
                           "atbaseline"
                                               "atesurgeries"
                                                                  "atmiv"
#>
#>
   [9] "atoutcome"
                                               "atstudyterminat" "attreatment"
                           "atsae"
#> [13] "baseline"
                           "esurgeries"
                                               "outcome"
                                                                  "sae"
#> [17] "studyterminat"
                           "treatment"
```

Substituting env with .GlobalEnv instead would also be an option and would make the data.frames immediately accessible without having to refer to an environment.

# Frequent warning messages

Certain warning messages can occur quite frequently when running read\_secuTrial(). Some of them may call for deliberate action and thus it is important to understand them. We briefly mentioned some of them earlier in this document but will now more closely explain how they can be interpreted.

Please note that warning messages may "pile up" depending on the export you are reading. For example this may happen if there are many date variables with incomplete data. This is no reason for concern. We suggest that you read them and interpret them based on the explanations below. We use a\_form\_name and a\_variable\_name as place holders in the examples. If in doubt you can always work with the raw data because it is never overwritten.

## Dates

The below warning tells you that some data in a date variable could not be converted during the process of date conversion (i.e. dates\_secuTrial()). This usually occurs if incomplete date entries are present. Since the raw data is not overwritten but rather a variable\_name.date or variable\_name.datetime column are added to the dataset you can specifically see which values could not be converted because the raw data will contain data while the corresponding .date/.datetime entires will be NA. The warning also indicates where to look. The dummy example below indicates to look at the variable\_name in form a\_form\_name.

```
#> Warning: In dates_secuTrial.data.frame(tmp, datevars, timevars, dateformat, :
#> Not all dates were converted for
#> variable: 'a_variable_name'
```

#> in form: 'a\_form\_name'
#> This is likely due to incomplete date entries.

## Factors

In some cases secuTrial allows differently coded data to be decoded to the same target value for the same variable. For instance this can happen if hierarchical lookuptables have been implemented in the database. Because this interferes with the factorization (i.e. factorize\_secuTrial()) we add the code to the duplicate decoded value and return the below message to make you aware.

If you run into this warning message we suggest running the table() function on the variable in question. This will likely clarify the above explanation.

```
#> Warning: In factorize_secuTrial.data.frame(curr_form_data, cl = object$cl, :
#> Duplicate values found during factorization of a_variable_name
```

## Labels

Sometimes the labels of variables in a secuTrial database implementation may be changed after release of the database. In these cases all labels (current and previous versions) are added to the label attribute during labelling (i.e. label\_secuTrial()) and the below warning is triggered. It indicates which variables in which forms are affected.

```
#> Warning: In label_secuTrial.secuTrialdata(d) :
#> The labels attribute may be longer than 1 for the following variables and forms.
#> Likely the label was changed from its original state in the secuTrial project setup.
#> variables: a_variable_name
#> forms: a_form_name
```

# Merging forms in the secuTrialdata object

Naturally, you will sometimes need to merge/join some of the data from the individual form data stored in your secuTrialdata object. To achieve this you can use the base R merge() function. For our dataset we might be interested in merging the baseline form data with that of the treatment form. For this we can use the mnpcvpid which uniquely identifies each participant visit. Since we are only interested in the rando\_treatment variable we will shrink the data in the treatment form prior to merging.

```
treatment_shrink <- ctu05_data$treatment[, c("mnpcvpid", "rando_treatment")]</pre>
```

Because we do not want to drop non-matching rows from **baseline** we set **all.x** = **TRUE**. As you can see from the dim() calls, one column has been added after the merge. This corresponds to the **rando\_treatment** variable.

#> [1] 17 108

Another common task may be to merge repetition form data to its parent form. In our case esurgeries can be naively merged with baseline via the mnpdocid (from the secuTrial manual: "Each eCRF document record has a unique document identifier."):

bl\_surg <- merge(x = ctu05\_data\$baseline, y = ctu05\_data\$esurgeries, by = "mnpdocid")

Please note, that such naive merging can cause duplication of data if the ids that the merge is directed by are not unique. This also happened during the production of bl\_surg in the code above. Participant "RPACK-INS-012" exhibits the mnpdocid 234 twice in the esurgeries repetition form which causes a duplication of the baseline data matching mnpdocid 234.

Lets briefly illustrate the consequences by looking at a table() of the height variable from the baseline form before and after merging.

```
# before merge
table(ctu05_data$baseline$height)
#>
                  160 167.9 170.3 170.4 180 180.1 190.2
#> 110.1
       150 150.1
#>
  1
          1 1 1 1 1 1 3 3 1
# after merge
table(bl_surg$height)
#>
#> 110.1
        150 150.1
                  160 167.9 170.3 170.4
                                      180 180.1 190.2
#>
                    1 1 1 1
                                        4 3
     1
          1
              1
                                                  1
```

A closer look reveals that 180 now appears four times instead of three, which can be attributed to the duplication. This is not a favourable outcome because it can cause confusion and misinterpretation. A better approach is to change the structure of your repetition form before merging to make the ids you merge by unique. For this you need to investigate which data you would like to merge and design an appropriate stategy. In our example case we are interested in the surgery\_organ. Of course we also need to drag the mnpdocid along to perform the actual merge.

```
# write a temporary object
surg <- ctu05_data$esurgeries[, c("mnpdocid", "surgery_organ.factor")]
# only retain non NA rows
surg <- surg[which(! is.na(surg$surgery_organ.factor)), ]
# show it
surg
#> mnpdocid surgery_organ.factor
#> 12 234 Stomach
#> 13 234 Other
```

In order to prevent duplication we can restructure the data before merging.

```
library(tidyr) # pivot_wider
# add a count
surg$count <- 1</pre>
# show the data
surg
#>
      mnpdocid surgery_organ.factor count
#> 12
           234
                              Stomach
                                           1
#> 13
            234
                                Other
                                           1
# make it wide
surg_wide <- pivot_wider(surg, names_from = surgery_organ.factor, values_from = count)</pre>
# show the wide data
surg_wide
#> # A tibble: 1 x 3
#>
   mnpdocid Stomach Other
#>
        \langle int \rangle
               <dbl> <dbl>
#> 1
          234
                     1
                            1
```

Checking the dimensions before and after merging reveals that the structure, especially the line count, remains the same except for the data added from the esurgeries repetition form (i.e. Stomach and Other). Also, as expected, the table() of the height variable returns the expected result (i.e. 180 is present three not four times).

```
# merge
bl_surg_no_dup <- merge(x = ctu05_data$baseline, y = surg_wide,</pre>
                      by = "mnpdocid", all.x = TRUE)
# compare dimensions
dim(bl_surg_no_dup)
#> [1] 17 109
dim(ctu05 data$baseline)
#> [1] 17 107
# check the height variable
table(bl_surg_no_dup$height)
#>
                     160 167.9 170.3 170.4
#> 110.1
         150 150.1
                                            180 180.1 190.2
#>
     1
            1 1 1 1 1 1
                                              3
                                                  3
                                                        1
```

The above description only provides a very brief and simplified example. Merging strategies need to be individually tailored and require a good understanding of the data at hand. The links\_secuTrial() function may be helpful to understand which variables will allow you to merge forms.

# A note on mnp\* variables

There is a plethora of variables in the tables of secuTrial exports whose names start with mnp. These are metadata variables which are e.g. important to logically link the different tables. Explaining them all is beyond the scope of this vignette. For detailed explanations, please refer to the secuTrial "Export Formats" user manual.

```
sessionInfo()
#> R version 4.4.0 (2024-04-24 ucrt)
#> Platform: x86_64-w64-mingw32/x64
#> Running under: Windows 10 x64 (build 19045)
#>
#> Matrix products: default
#>
#>
#> locale:
#> [1] LC_COLLATE=German_Switzerland.utf8 LC_CTYPE=German_Switzerland.utf8
#> [3] LC_MONETARY=German_Switzerland.utf8 LC_NUMERIC=C
#> [5] LC_TIME=German_Switzerland.utf8
#>
#> time zone: Europe/Zurich
#> tzcode source: internal
#>
#> attached base packages:
              graphics grDevices utils
#> [1] stats
                                           datasets methods
                                                                base
#>
#> other attached packages:
#> [1] tidyr_1.3.1
                      secuTrialR_1.3.3
#>
#> loaded via a namespace (and not attached):
#> [1] bit_4.0.5
                       highr_0.11
                                         crayon_1.5.2
                                                           dplyr_1.1.4
#> [5] compiler_4.4.0 tidyselect_1.2.1 stringr_1.5.1
                                                           parallel_4.4.0
#> [9] yaml_2.3.8
                     fastmap_1.2.0 readxl_1.4.3
                                                          readr_2.1.5
#> [13] R6 2.5.1
                       generics_0.1.3 knitr_1.46
                                                           forcats 1.0.0
                      lubridate_1.9.3 tufte_0.13
#> [17] tibble_3.2.1
                                                           pillar_1.9.0
#> [21] tzdb_0.4.0
                       rlang_1.1.3
                                        utf8_1.2.4
                                                           stringi_1.8.4
                      bit64_4.0.5 timechange_0.3.0
magrittr_2.0.3 digest_0.6.35
#> [25] xfun_0.44
                                         timechange_0.3.0 cli_3.6.2
#> [29] withr_3.0.0
                                                          vroom_1.6.5
#> [33] rstudioapi_0.16.0 haven_2.5.4
                                         hms_1.1.3
                                                           lifecycle_1.0.4
#> [37] vctrs_0.6.5 evaluate_0.23
                                          glue_1.7.0
                                                           cellranger_1.1.0
#> [41] fansi_1.0.6
                     rmarkdown_2.27
                                          purrr_1.0.2
                                                           tools_4.4.0
#> [45] pkgconfig_2.0.3 htmltools_0.5.8.1
```

#### Disclaimer

The descriptions of the secuTrial exports used in this vignette and other secuTrialR documentation correspond

to our understanding of them and come with no warranty. For in depth details please refer to the original secuTrial manuals.