

secuTrialR - a walkthrough

Patrick R. Wright, Milica Markovic, Alan G. Haynes

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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 ≥ 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] '1.0.8'
```

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.

```
ctu05_data_location <- system.file("extdata", "sT_exports", "exp_opt",
                                   "s_export_CSV-xls-CTU05_all_info.zip",
                                   package = "secuTrialR")
```

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 configuraion.

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.

```
print(ctu05_data)
#> secuTrial data imported from:
#> /tmp/Rtmp15os6n/Rinst7a6f11f05661/secuTrialR/extdata/sT_exports/exp_opt/
#> s_export_CSV-xls_CTU05_all_info.zip
#>      table nrow ncol meta original_name
#>      vp      4  12 TRUE      vp.xls
#>      vpfs     8   2 TRUE     vpfs.xls
#>      fs       8   8 TRUE      fs.xls
#>      qs      29   8 TRUE      qs.xls
#>      is      85   9 TRUE      is.xls
#>      ctr       3   3 TRUE      ctr.xls
#>      cn      11  15 TRUE      cn.xls
#>      atcn     0   9 TRUE      atcn.xls
#>      atcvp    0  16 TRUE     atcvp.xls
#>      qac      0  12 TRUE      qac.xls
#>      cts      0  10 TRUE      cts.xls
#>      miv      0  10 TRUE      miv.xls
#>      atmiv    0  15 FALSE     atmiv.xls
#>      baseline 17 107 FALSE     baseline.xls
#>      atbaseline 0  79 FALSE     atbaseline.xls
#>      outcome  13  48 FALSE     outcome.xls
#>      atoutcome 5  47 FALSE     atoutcome.xls
#>      treatment 11  44 FALSE     treatment.xls
#>      attreatment 0  45 FALSE     attreatment.xls
#>      allmedi  17  47 FALSE     allmedi.xls
#>      atallmedi 2  47 FALSE     atallmedi.xls
#>      studyterminat 10 41 FALSE     studyterminat.xls
#>      atstudyterminat 1 39 FALSE     atstudyterminat.xls
#>      ae       1  66 FALSE     ae.xls
#>      atae     0  58 FALSE     atae.xls
#>      sae      2  64 FALSE     sae.xls
#>      atsae    0  57 FALSE     atsae.xls
#>      esurgeries 18  11 FALSE     esurgeries.xls
#>      atesurgeries 0   9 FALSE     atesurgeries.xls
#>      cl      205   3 TRUE      cl.xls
#>      atae1    0  20 FALSE     atae1.xls
```

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 to 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$treatment$trando_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 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: 5.5.1.10
#> Time of export on server: 03.10.2019 - 14:43:49 (CEST)
#> Project version: (20.06.2019 - 11:22:04 (CEST))
#> Exported with short names
#> File extension: xls
#> Seperator: ' '
#> 32 files exported
#> including 13 metadata tables
#> Reference values exported - factorize possible
#> Metadata tables:
#>           type exportname available
#>           forms      fs      TRUE
#>           casenodes   cn      TRUE
#>           centres    ctr      TRUE
#>           items      is      TRUE
#>           questions  qs      TRUE
#>           queries    qac      TRUE
#>           visitplan  vp      TRUE
#>           visitplanforms  vpfs  TRUE
#>           atcasenodes  atcn    TRUE
#>           atcasevisitplans  atcvp  TRUE
#>           comments    cts      TRUE
#>           miu         miu      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.

```
names(ctu05_data$export_options)
#> [1] "sep" "date_format" "datetime_format"
#> [4] "date_format_meta" "na.strings" "short_names"
#> [7] "is_zip" "is_rectangular" "audit_trail"
#> [10] "column_names" "lang_not_supported" "dict_items"
#> [13] "refvals_separate" "add_id" "lab_id"
#> [16] "meta_names" "meta_available" "duplicate_meta"
#> [19] "all_files" "data_files" "data_names"
#> [22] "file_end" "extension" "data_dir"
#> [25] "secuTrial_version" "project_version" "project_name"
#> [28] "format_info" "time_of_export" "encoding"
#> [31] "form_status" "centre_info" "hidden_fields"
#> [34] "structure" "proj_setup" "factorized"
#> [37] "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_participants(ctu05_data)
#>   mnppid      mnpaid mnpctrid      mnpctrname
#> 1  1204 RPACK-CBE-001    462 Charité Berlin (RPACK)
#> 2  1205 RPACK-CBE-002    462 Charité Berlin (RPACK)
#> 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)
#> 8  1211 RPACK-INS-013    461 Inselspital Bern (RPACK)
#> 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.

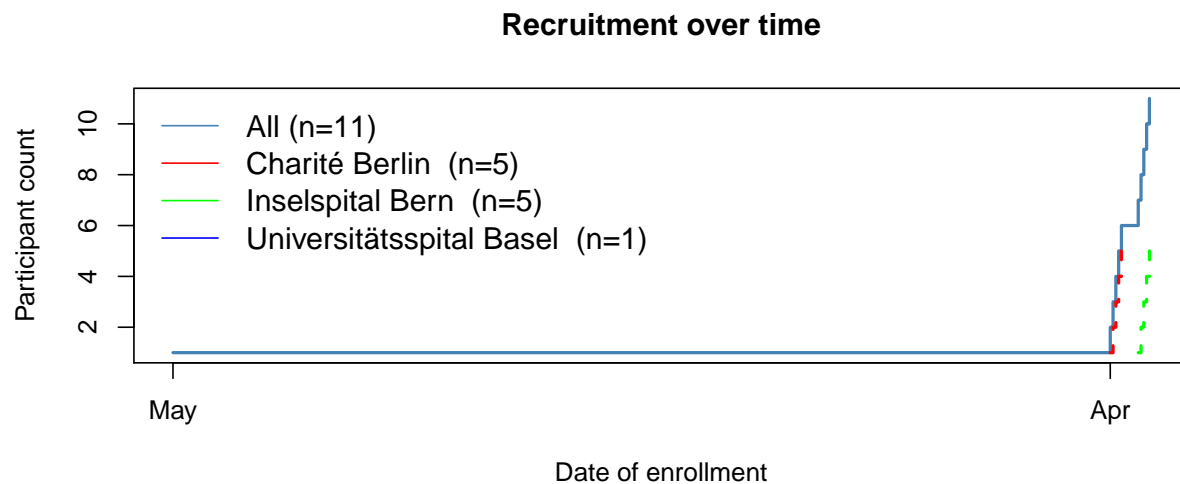
```
annual_recruitment(ctu05_data)
#>
#> 1           Center Total 2018 2019
#> 2           All      11    1    10
#> 3 Charité Berlin (RPACK)    5    0    5
#> 4 Inselspital Bern (RPACK)  5    0    5
#> 5 Universitätsspital Basel (RPACK)  1    1    0
```

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.

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

It is also possible to plot the recruitment over time.

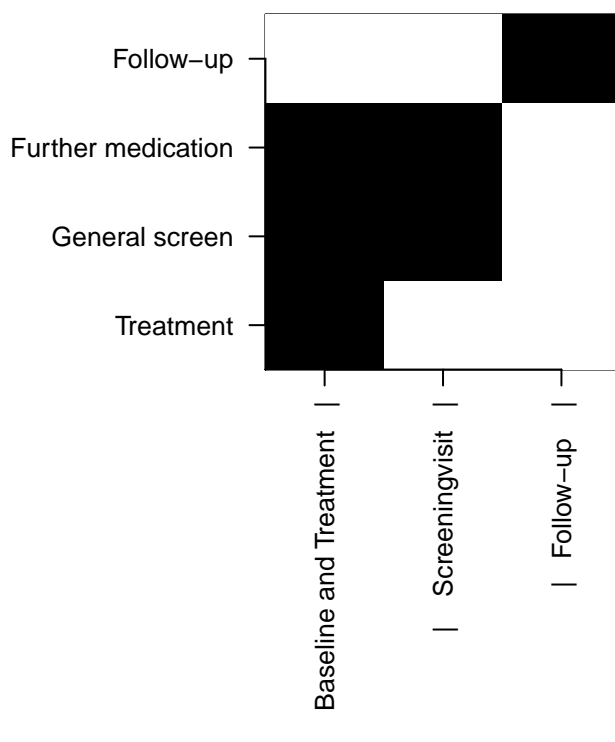
```
plot_recruitment(ctu05_data, cex = 1.2, rm_regex = "\\(..*\\)$")
```



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).

```
vs <- visit_structure(ctu05_data)
plot(vs)
```



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)
tail(fss, n = 5)
#>      form_name partly_filled completely_filled empty with_warnings
#> 6      baseline          3             14      0           0
#> 7      outcome          1             12      0           0
#> 8          sae           0              2      0           0
#> 9 studyterminat         0             10      0           0
#> 10     treatment        0             11      0           0
#>      with_errors partly_filled.percent completely_filled.percent empty.percent
#> 6          0          0.17647059          0.8235294          0
#> 7          0          0.07692308          0.9230769          0
#> 8          0          0.00000000          1.0000000          0
#> 9          0          0.00000000          1.0000000          0
#> 10         0          0.00000000          1.0000000          0
#>      with_warnings.percent with_errors.percent form_count
```

```
#> 6          0          0          17
#> 7          0          0          13
#> 8          0          0           2
#> 9          0          0          10
#> 10         0          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)
# 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              1             2      0             0
#> 6 RPACK-INS-011 baseline              1             0      0             0
#> with_errors
#> 1          0
#> 2          0
#> 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",
                                     "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.

ctu06_v2 <- read_secuTrial(system.file("extdata", "sT_exports", "change_tracking",
                                     "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, preferring 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)
```

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")
centres <- c("Inselsspital Bern (RPACK)", "Universitätsspital Basel (RPACK)")

# 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)
#> 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)
#> 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"
```

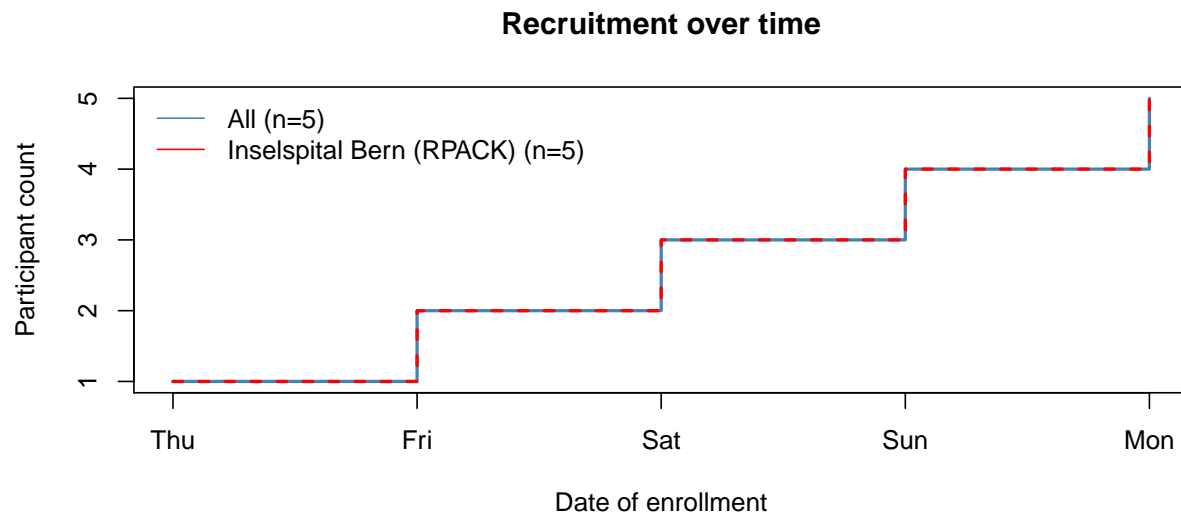
If you subset based on centres all traces of deleted centres will be removed. If you remove based on participant ids all traces of deleted participants will be removed.

```
# only Berlin remains
ctu05_data_berlin$ctr
#>   mnpctrnid      mnpctrname mnpcname
#> 1      462 Charité Berlin (RPACK)    NA

# all centres remain even though all three participant ids are from Bern
ctu05_data_pids$ctr
#>   mnpctrnid      mnpctrname mnpcname
#> 1      462      Charité Berlin (RPACK)    NA
#> 2      461      Inselsspital Bern (RPACK)    NA
#> 3      441      Universitätsspital Basel (RPACK)    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.

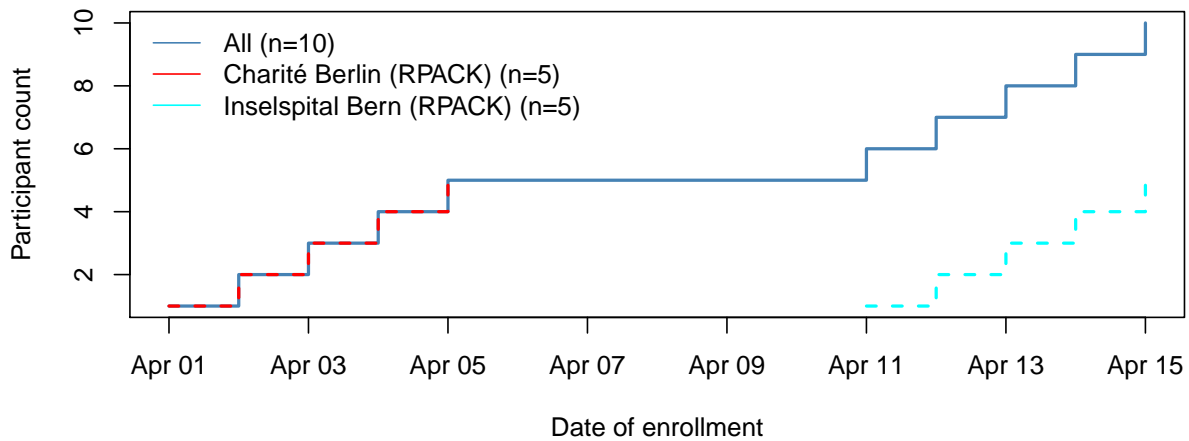
```
# keep only Bern
ctu05_data_bern <- subset_secuTrial(ctu05_data, centre = "Inselspital Bern (RPACK)")
#> If you changed any labels in the secuTrialdata object manually these will be reset to their original
# plot
plot_recruitment(ctu05_data_bern)
```



... or Bern and Berlin.

```
# keep only Bern and Berlin
ctu05_data_bern_berlin <- subset_secuTrial(ctu05_data,
                                           centre = c("Inselspital Bern (RPACK)",
                                                     "Charité Berlin (RPACK)"))
#> If you changed any labels in the secuTrialdata object manually these will be reset to their original
# plot
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 demonstrate `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.

```
server <- "server.secutrial.com"
instance <- "ST21-setup-DataCapture"
customer <- "TES"
project <- "7036"

# make three links with the first three baseline docids
bl_docids <- head(ctu05_data$baseline$mnpdocid, n = 3)
links <- build_secuTrial_url(server, instance, customer,
                             project, bl_docids)
```

These are the links:

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

<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=TES&projectid=7036&docid=187>

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" "atmiiv"
#> [9] "atoutcome" "atsae" "atstudyterminat" "attreatment"
#> [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` entries will be `NA`. The **warning** also indicates where to look. The dummy example below indicates to look at the variable `a_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 `mnpvcpid` 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("mnpvcpid", "rando_treatment")]
```

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.

```
bl_treat <- merge(x = ctu05_data$baseline, y = treatment_shrink,
                 by = "mnpvcpid", all.x = TRUE)
# check dimensions
dim(ctu05_data$baseline)
#> [1] 17 107
dim(bl_treat)
#> [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.

```
table(ctu05_data$esurgeries$mnpdocid)
#>
#> 180 184 187 191 199 203 211 216 220 222 230 234 238 243 249 255 265
#>  1  1  1  1  1  1  1  1  1  1  1  2  1  1  1  1  1
```

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)
#>
#> 110.1  150 150.1  160 167.9 170.3 170.4  180 180.1 190.2
#>    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    1    1    1    4    3    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 strategy. 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
# 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)
# show the wide data
surg_wide
#> # A tibble: 1 x 3
#>   mnpdocid Stomach Other
#>   <int>   <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,
                       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)
#>
#> 110.1  150 150.1  160 167.9 170.3 170.4  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 3.6.3 RC (2020-02-21 r77847)
#> Platform: x86_64-pc-linux-gnu (64-bit)
#> Running under: Ubuntu 18.04.5 LTS
#>
#> Matrix products: default
#> BLAS: /usr/lib/x86_64-linux-gnu/blas/libblas.so.3.7.1
#> LAPACK: /usr/lib/x86_64-linux-gnu/lapack/liblapack.so.3.7.1
#>
#> locale:
#> [1] LC_CTYPE=C.UTF-8      LC_NUMERIC=C           LC_TIME=C.UTF-8
#> [4] LC_COLLATE=C           LC_MONETARY=C.UTF-8   LC_MESSAGES=C.UTF-8
#> [7] LC_PAPER=C.UTF-8      LC_NAME=C              LC_ADDRESS=C
#> [10] LC_TELEPHONE=C        LC_MEASUREMENT=C.UTF-8 LC_IDENTIFICATION=C
#>
#> attached base packages:
#> [1] stats      graphics  grDevices  utils      datasets  methods    base
#>
#> other attached packages:
#> [1] tidyr_1.0.0      secuTrialR_1.0.8
#>
#> loaded via a namespace (and not attached):
#> [1] Rcpp_1.0.5      knitr_1.30       magrittr_1.5     hms_0.5.2
#> [5] tidyselect_1.1.0 R6_2.4.0         rlang_0.4.8     fansi_0.4.0
#> [9] stringr_1.4.0   dplyr_1.0.0     tools_3.6.3     xfun_0.19
#> [13] utf8_1.1.4      cli_2.1.0        htmltools_0.4.0 assertthat_0.2.1
#> [17] readxl_1.3.1    yaml_2.2.0       digest_0.6.27   tibble_2.1.3
#> [21] lifecycle_0.2.0 crayon_1.3.4     purrr_0.3.3     readr_1.3.1
#> [25] vctrs_0.3.1     glue_1.4.1       evaluate_0.14    haven_2.3.1
#> [29] rmarkdown_2.5   stringi_1.4.3    cellranger_1.1.0 compiler_3.6.3
#> [33] pillar_1.4.2    forcats_0.4.0   generics_0.0.2  lubridate_1.7.9
#> [37] tufte_0.5       pkgconfig_2.0.3

```

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.