Package: SwissASR (via r-universe)

August 29, 2024

Title Automated Completion of the SwissEthics Annual Safety Report

Version 0.5.2

Description Completing the SwissEthics Annual Safety Report can be tiresome. This package eases the pain by providing an automated method to fill it out.

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URL https://github.com/CTU-Bern/SwissASR, https://ctu-bern.github.io/SwissASR/

Encoding UTF-8

LazyData true

Roxygen list(markdown = TRUE)

RoxygenNote 7.2.3

Depends R (>= 2.10)

Imports flextable, glue, magrittr, officer, stringr, tibble, doconv

Suggests rstudioapi

Repository https://ctu-bern.r-universe.dev

RemoteUrl https://github.com/CTU-Bern/SwissASR

RemoteRef HEAD

RemoteSha b83ae81dd367c3cf79edcbeb9b16b31985b783a1

Contents

asr *Fill the Annual Safety Report template*

Description

This function fills out the SwissEthics annual safety report template with a much as possible. Minor (formatting) changes will still be required after generation of the report.

Usage

```
asr(
  data,
  target = "tmp.docx",
  trial_title = "TRIAL NAME",
  protocol_number = "default",
  basec_number = "default",
  snctp_number = "default",
  swissmedic_number = "default",
  ec_name = "default",
  tr_number = "default",
  product_name = "default",
  sponsor_contact = "default name, default number, default email",
  inst_name_address = "default name, default address",
  n_centers_t = "default",
  n_centers_p = "default",
  n_centers_c = "default",
  n_centers_o = "default",
  n_pat_t = 500,
  n_pat_e = 300,
  n_pat_c = 100,
  n_pat_p = 15,
  n_centers_t_ch = "default",
  n_centers_p_ch = "default",
  n_centers_c_ch = "default",
  n_centers_o_ch = "default",
  n_pat_t_ch = 500,
  n_pat_e_ch = 300,
  n_pat_c_ch = 100,
  n_pat_p_ch = 15,
  n_per_arm = c(grp1 = 150, grp2 = 150),
  report_date = format(Sys.Date(), format = "%d/%m/%Y"),
  period_from = as.Date("2020-11-02"),
  period_to = as.Date("2020-11-17"),
  template = system.file("extdata/clino_annual_safety_report_fm.docx", package =
    "SwissASR"),
  international = FALSE,
  trial_type = "imp",
```

```
  var_class = "class",
  var_sae_n = "sae_n",
  var_part_id = "record_id",
  var_age = "age",
  var_sex = "sex",
  var_country = "country",
  var_site = "site",
  var_sae = "sae",
  var_date_onset = "sae_date",
  var_trt = "trt",
  var_date_trt_start = "sae_trtstart",
  var_date_trt_stop = "sae_trtstop",
  var_outcome = "outcome",
  var_comment = "comment",
  var_relation = "related",
  var_expected = "expected",
  var_devdef = "devdef",
  var_devattr = "devattr",
  var_devint = "devint",
  var_safetymeasure = "safetymeasure",
  var_tx = NULL
)
```

Arguments

`data`	dataframe containing safety data
`target`	filename to save the report to
`trial_title`	name of the trial
`protocol_number`	trial code/protocol number
`basec_number`	BASEC number
`snctp_number`	SNCTP number
`swissmedic_number`	Swissmedic number
`ec_name`	EC name (Lead EC and/concerned EC)
`tr_number`	Number for Transplantation Clinical Trials (FOPH number)
`product_name`	product name or intervention
`sponsor_contact`	contact details of sponsor(-investigator)
`inst_name_address`	name and address of institute
`n_centers_t`	total number of participating centres
`n_centers_p`	planned number of participating centres
`n_centers_c`	number of closed centres
`n_centers_o`	number of open centres

n_pat_t	target number of participants
n_pat_e	number of enrolled participants
n_pat_c	number of completed participants
n_pat_p	number of prematurely terminated participants
n_centers_t_ch	total number of participating centres in CH
n_centers_p_ch	planned number of participating centres in CH
n_centers_c_ch	number of closed centres in CH
n_centers_o_ch	number of open centres in CH
n_pat_t_ch	target number of participants in CH
n_pat_e_ch	number of enrolled participants in CH
n_pat_c_ch	number of completed participants in CH
n_pat_p_ch	number of prematurely terminated participants in CH
n_per_arm	number of enrolled participants per arm, list with group 1 and 2, define here the names of your groups as in the data
report_date	report date
period_from	start of reporting period
period_to	end of reporting period
template	path to template file
international	internation or national trial (logical)
trial_type	one of imp, medical device, other. Abbreviations OK.
var_class	variable containing SAE class. Options allowed are "SAE", "SADR", "SUSAR"
var_sae_n	variable containing SAE ID
var_part_id	variable containing participant ID
var_age	variable containing participant age
var_sex	variable containing participant sex
var_country	variable containing participants country
var_site	variable containing participants site
var_sae	variable containing SAE type (description)
var_date_onset	variable containing the date the SAE occured
var_trt	variable containing the treatment used to alleviate the SAE
var_date_trt_start	variable containing the date that the treatment started
var_date_trt_stop	variable containing the date that the treatment ended
var_outcome	variable containing the outcome of the SAE
var_comment	variable containing any comment
var_relation	variable containing the relationship to randomized intervention
var_expected	variable saying whether the SAE was expected

var_devdef	variable containing whether the SAE is a device deficiency
var_devattr	variable containing whether the SAE is attributable to the device
var_devint	variable containing whether the SAE is attributable to an intervention in the trial
var_safetymeasure	variable containing whether the SAE required safety related measures
var_tx	variable indicating the intervention group. If provided, this variable will be included in the line listing

Details

Use of the var_tx argument results in the indicated variable being included in the line listing.

Value

nothing in R, creates a docx file in the target location

Examples

```
data(asr_sae)
file <- tempfile("asr", fileext = ".docx")
asr(asr_sae, file)

# # more usual use will require passing more information:
# asr(asr_sae, file,
#     # trial info
#     trial_title = "Example Trial Name",
#     protocol_number = "20221002130",
#     basec_number = "",
#     snctp_number = "202200458",
#     swissmedic_number = "....",
#     ec_name = "Kantonale Ethikskommision Bern",
#     tr_number = "",
#     product_name = "Drug name",
#     international = FALSE,
#     trial_type = "imp",
#     # Sponsor info
#     sponsor_contact = "Sponsor name, Sponsor phone number, Sponsor email",
#     inst_name_address = "Institute name, Institute address",
#     # site info
#     n_centers_t = 20,        # total number
#     n_centers_p = "default", # planned
#     n_centers_c = "default", # closed
#     n_centers_o = "default", # open
#     # participant info
#     n_pat_t = 1000,          # target
#     n_pat_e = 300,           # enrolled
#     n_pat_c = 0,             # complete
#     n_pat_p = 0,             # prematurely terminated
#     # report info
#     report_date = format(Sys.Date(), format = "%d/%m/%Y"),
#     period_from = as.Date("2020-11-02"),
```

```
#     period_to = as.Date("2020-11-17"),
#     # variable mapping
#     var_class = "class",
#     var_sae_n = "sae_n", #sae ID
#     var_part_id = "record_id", #participant ID
#     var_age = "age",
#     var_sex ="sex",
#     var_country = "country",
#     var_site = "site",
#     var_sae = "sae",
#     var_date_onset = "sae_date",
#     var_trt = "trt",
#     var_date_trt_start = "sae_trtstart",
#     var_date_trt_stop = "sae_trtstop",
#     var_outcome = "outcome",
#     var_comment = "comment",
#     var_relation = "related",
#     var_expected = "expected",
#     var_safetymeasure = "safetymeasure"
#     )
```

`asr_dataprep` *Prepare data for the* `asr` *function*

Description

This function allows the use of the `asr_safety_summary` function outside of the normal `asr` function, which might be desirable to get an overview of the information in a different format to MS Word.

Usage

```
asr_dataprep(
  data,
  trial_type = "imp",
  international = FALSE,
  period_from = NA,
  period_to = NA,
  var_class = "class",
  var_sae_n = "sae_n",
  var_part_id = "record_id",
  var_age = "age",
  var_sex = "sex",
  var_country = "country",
  var_site = "site",
  var_sae = "sae",
```

```
  var_date_onset = "sae_date",
  var_trt = "trt",
  var_date_trt_start = "sae_trtstart",
  var_date_trt_stop = "sae_trtstop",
  var_outcome = "outcome",
  var_comment = "comment",
  var_relation = "related",
  var_expected = "expected",
  var_devdef = "devdef",
  var_devattr = "devattr",
  var_devint = "devint",
  var_safetymeasure = "safetymeasure",
  var_tx = NULL
)
```

Arguments

`data`	dataframe containing safety data
`trial_type`	one of `imp`, `medical device`, `other`. Abbreviations OK.
`international`	internation or national trial (logical)
`period_from`	start of reporting period
`period_to`	end of reporting period
`var_class`	variable containing SAE class. Options allowed are "SAE", "SADR", "SUSAR"
`var_sae_n`	variable containing SAE ID
`var_part_id`	variable containing participant ID
`var_age`	variable containing participant age
`var_sex`	variable containing participant sex
`var_country`	variable containing participants country
`var_site`	variable containing participants site
`var_sae`	variable containing SAE type (description)
`var_date_onset`	variable containing the date the SAE occured
`var_trt`	variable containing the treatment used to alleviate the SAE
`var_date_trt_start`	variable containing the date that the treatment started
`var_date_trt_stop`	variable containing the date that the treatment ended
`var_outcome`	variable containing the outcome of the SAE
`var_comment`	variable containing any comment
`var_relation`	variable containing the relationship to randomized intervention
`var_expected`	variable saying whether the SAE was expected
`var_devdef`	variable containing whether the SAE is a device deficiency
`var_devattr`	variable containing whether the SAE is attributable to the device

`var_devint` variable containing whether the SAE is attributable to an intervention in the trial

`var_safetymeasure` variable containing whether the SAE required safety related measures

`var_tx` variable indicating the intervention group. If provided, this variable will be included in the line listing

Value

a list of 2 dataframes (`data` containing all data submitted to the function and `period_data` which contains only the data for the relevant period) with variables renamed to those expected by `asr_safety_summary`

Examples

```
data(asr_sae)
# IMP
asr_dataprep(asr_sae, period_from = as.Date("2020-10-10"), period_to = as.Date("2021-10-10"))
asr_dataprep(asr_sae, period_from = min(asr_sae$sae_date), period_to = Sys.Date())
```

---

asr_sae *Demonstration data set*

Description

Simulated recruitment data from three sites. Each row represents an SAE. Sites one and two started on 2020-07-01, site three on 2020-09-01.

Usage

```
asr_sae
```

Format

A data frame with the following variables:

sae_date The date that the SAE occured

record_id Participant ID

age Participant age

sex Participant sex

country Participant's country

site Which site the participant was recruited into

sae Description of the SAE

intervention Intervention arm

outcome SAE outcome (e.g. fatal, sequel, improved, resolved)

comment A comment about the SAE

trt How was the participant treated?

class SAE classification (SUSAR, SADR, ...)

expected Was the SAE expected

devdef (For device trials) was the SAE a device deficiency?

devattr (For device trials) was the SAE attributable to the device?

devint (For device trials) was the SAE attributable to the intervention?

safetymeasure (For device trials) was the SAE a health hazards that required safety-related measures?

sae_n SAE number/identifier

sae_trtstop SAE treatment stop

sae_trtstart SAE treatment start

related Was the SAE related to the intervention

`asr_safety_summary` *Summarize safety data*

Description

This function creates the text and summary table for the report.

Usage

```
asr_safety_summary(data, period_data, trial_type, n_pat_e, n_per_arm)
```

Arguments

`data`	SAE data
`period_data`	SAE data restricted to a specific period
`trial_type`	trial type (`imp`, `medical device` or `other`)
`n_pat_e`	Number of enrolled participants
`n_per_arm`	Number of participants enrolled per arm

Value

txt The sentences required for the report

tab The summary table required for the report

tab_map Mapping between the variable name in `tab` and a nicer label

Examples

```
data(asr_sae)
# IMP
prepped <- asr_dataprep(asr_sae,
                        period_from = as.Date("2020-10-10"),
                        period_to = as.Date("2021-10-10")
                        )
asr_safety_summary(data = prepped$data, period_data = prepped$period_data,
                   "imp", 60, n_per_arm = list(grp1 = 150, grp2 = 150))

# medical devices
prepped <- asr_dataprep(asr_sae, period_from = as.Date("2020-10-10"),
                        period_to = as.Date("2021-10-10"), trial_type = "m")
asr_safety_summary(data = prepped$data,
                           period_data = prepped$period_data, "m", 60,
                            n_per_arm = list(grp1 = NA, grp2 = NA))

# other trial
asr_safety_summary(data = prepped$data, period_data = prepped$period_data, "o", 60,
 n_per_arm = list(grp1 = 150, grp2 = 150))

# tpr trial
asr_safety_summary(data = prepped$data, period_data = prepped$period_data, "t", 60,
 n_per_arm = list(grp1 = 150, grp2 = 150))
```

Index