Package 'gtreg'

November 17, 2023

```
Title Regulatory Tables for Clinical Research
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Description Creates tables suitable for regulatory agency submission by
      leveraging the 'gtsummary' package as the back end. Tables can be exported
      to HTML, Word, PDF and more. Highly customized outputs are
      available by utilizing existing styling functions from 'gtsummary' as
      well as custom options designed for regulatory tables.
License GPL (>= 3)
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      https://shannonpileggi.github.io/gtreg/
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Description

Returns a data frame that has an observation for each patient in the study, with combinations for each ID, SOC, and AE. The returned data frame includes new logical columns "..ae.." and "..soc.." indicating whether that row should be included when tabulating the AE table. When multiple AEs of the same type are observed, the AE with the largest by= value is the observation to be used in the tabulation.

Usage

```
.complete_ae_data(
   data,
   id,
   ae,
   soc = NULL,
   by = NULL,
   strata = NULL,
   id_df = NULL,
   by_values = NULL,
   missing_text = "Unknown",
   missing_location = "first"
)
```

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Arguments

data	Data frame					
id	String variable name of the patient ID					
ae	String variable name of the adverse event column					
soc	Optional string variable name of the system organ class column					
by	Optional string variable to split results by, e.g. report AEs by grade or attribution					
strata	Optional string variable to stratify results by, e.g. report AEs summaries by treatment group					
id_df	Optional data frame of complete id values and strata to achieve correct base n for the situation in which not all subjects experience adverse events					
by_values	Optional vector of complete by values, listed in desired order, to achieve correct table structure for the situation in which an adverse event of a certain grade is not observed for a given soc					
missing_text	String that will be shown for missing levels of by=, Default is "Unknown"					
missing_location						
	location where the column summarizing values with missing levels by= will be located in the final table. Must be one of c("first", "last", "hide). Default is "first"					

Value

a tibble

Examples

```
df_adverse_events %>%
  .complete_ae_data(
    id = "patient_id",
    ae = "adverse_event",
    soc = "system_organ_class",
    by = "grade",
    strata = "trt"
)
```

add_overall_tbl_ae

Tabulate Overall Summary

Description

Tabulate Overall Summary

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Usage

```
## S3 method for class 'tbl_ae'
add_overall(x, across = NULL, ...)
## S3 method for class 'tbl_ae_count'
add_overall(x, across = NULL, ...)
## S3 method for class 'tbl_ae_focus'
add_overall(x, across = NULL, ...)
```

Arguments

x Object of class "tbl_ae", "tbl_ae_focus", or "tbl_ae_count"
across Specify the type of overall statistics to include.

• "both" adds summaries across both the by= and strata= levels

• "by" adds summaries across the by= levels

• "strata" adds summaries across the strata= levels

• "overall-only" adds a single overall column Default is all possible overall types.

... Not used

Value

Summary object of same input class

Notes

If the spanning headers are modified prior to the call of add_overall(), the ordering of the columns may not be correct.

Example Output

```
# Example 1 ------
add_overall_ex1 <-
    df_adverse_events %>%
    tbl_ae_count(
    ae = adverse_event,
    soc = system_organ_class,
    by = grade,
    strata = trt
) %>%
    add_overall() %>%
    modify_header(all_ae_cols() ~ "**Grade {by}**") %>%
    bold_labels()
```

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```
# Example 2 ------
add_overall_ex2 <-
 df_adverse_events %>%
 tbl_ae(
   id = patient_id,
   ae = adverse_event,
   soc = system_organ_class,
   by = grade
 ) %>%
 add_overall(across = 'by') %>%
 modify_header(all_ae_cols() ~ "**Grade {by}**") %>%
 bold_labels()
# Example 3 ------
add_overall_ex3 <-
 df_adverse_events %>%
 tbl_ae_focus(
   id = patient_id,
   include = c(any_complication, grade3_complication),
   ae = adverse_event,
   strata = trt
 ) %>%
 add_overall(across = 'strata')
# Example 4 ------
add_overall_ex4 <-
 df_adverse_events %>%
 tbl_ae(
   id = patient_id,
   ae = adverse_event,
   soc = system_organ_class,
   by = grade,
   strata = trt
 ) %>%
 add_overall(across = 'overall-only') %>%
 modify\_header(all\_ae\_cols() ~ "**Grade {by}**") ~ \%>\%
 bold_labels()
```

df_adverse_events

Simulated Adverse Event Database

Description

A data set containing reported AEs from a trial.

Usage

```
df_adverse_events
```

Format

```
A data frame with 100 rows—one row per patient per AE

patient_id Patient ID

trt Treatment Group

system_organ_class System Organ Class

adverse_event Adverse Event

grade Grade

drug_attribution Drug Attribution

any_complication Any Grade Complication
```

grade3_complication Grade 3+ Complication

```
df_patient_characteristics
```

Simulated Patient Characteristics Database

Description

Simulated Patient Characteristics Database

Usage

```
df_patient_characteristics
```

Format

A data frame with 100 rows-one row per patient

```
patient_id Patient ID

trt Treatment Group

age Patient Age

marker Biological Marker

status Study Status

discontinued Discontinued from Study

off_trt_ae Off Treatment Adverse Event
```

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inline_text_tbl_ae

Report Values from gtreg tables in-line

Description

Function allows users to report formatted and styled results from gtreg tables in-line.

Usage

```
## S3 method for class 'tbl_ae'
inline_text(x, row, column = NULL, ...)
## S3 method for class 'tbl_ae_count'
inline_text(x, row, column = NULL, ...)
## S3 method for class 'tbl_ae_focus'
inline_text(x, row, column = NULL, ...)
```

Arguments

```
x an object of class tbl_ae(), tbl_ae_count(), tbl_ae_focus()
row string indicating the AE or SOC to report
column column name of cell to report. Use show_header_names(x) to print all column names beside the current header.
... not used
```

Value

string

```
tbl <-
    df_adverse_events %>%
    tbl_ae(
    id = patient_id,
    ae = adverse_event,
    soc = system_organ_class,
    by = grade
    )
show_header_names(tbl)
inline_text(tbl, "Anaemia", column = stat_5)
```

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selectors

Column Selectors

Description

See the Table modifications article for examples.

- all_ae_cols(overall, unknown) selects all columns summarizing AE statistics. By default, unknown and overall columns are not selected.
- all_cols_in_strata(strata) selects all columns from specified stratum.
- all_overall_cols() selects all overall columns
- all_unknown_cols() selects all unknown columns

Usage

```
all_ae_cols(overall = FALSE, unknown = FALSE)
all_cols_in_strata(strata)
all_overall_cols()
all_unknown_cols()
```

Arguments

overall logical indicating whether to include the overall columns. Default is FALSE
unknown logical indicating whether to include the unknown or missing columns. Default is FALSE
strata character vector of the selected stratum

Value

selected columns

Example Output

See Also

```
gtsummary::all_stat_cols()
```

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Examples

```
selectors_ex1 <-
    df_adverse_events %>%
    dplyr::mutate(grade = ifelse(dplyr::row_number() == 1L, NA, grade)) %>%
    tbl_ae(
    id = patient_id,
    ae = adverse_event,
    soc = system_organ_class,
    by = grade
) %>%
    add_overall(across = 'by') %>%
    modify_header(
    all_ae_cols() ~ "**Grade {by}**",
    all_overall_cols() ~ "**Total**",
    all_unknown_cols() ~ "**Unknown Grade**"
)
```

style_xxx

Style numbers as x's

Description

The purpose of style_xxx() is to convert numeric values in summary tables to x's of consistent length for mock tables. See the Table shells vignette for detailed examples.

Usage

```
style_xxx(x, width = digits + 2, digits = 0)
```

Arguments

x a numeric or character vector
 width the width of output field of x's, including the decimal place
 digits the number of digits displayed after the decimal place

Value

a character vector

```
style_xxx(7:10, digits = 0)
style_xxx(7:10, digits = 1)
style_xxx(7:10, width = 2, digits = 0)
style_xxx(7:10, width = 5, digits = 2)
```

tbl_ae

tbl_ae Tabulate Adverse Events

Description

The function tabulates adverse events. One AE per ID will be counted in the resulting table. If a by= variable is passed and a patient experienced more than one of the same AE, the AE associated with the highest by= level will be included. For example, if a patient has two of the same AE and by = grade, the AE with the highest grade will be included. Similarly, if tabulations within system organ class are requested, the AE within SOC associated with the highest grade will be tabulated.

Usage

```
tbl_ae(
  data,
  id,
  ae,
  soc = NULL,
  by = NULL,
  strata = NULL,
  id_df = NULL,
  statistic = "{n} ({p})",
  by_values = NULL,
  digits = NULL,
  sort = NULL,
  sort = NULL,
  rero_symbol = "\U2014",
  missing_location = c("first", "last", "hide")
)
```

data	Data frame
id	Variable name of the patient ID
ae	Variable name of the adverse event column
soc	Variable name of the system organ class column
by	Variable to split results by, e.g. report AEs by grade
strata	Variable to stratify results by, e.g. report AEs summaries by treatment group
id_df	Optional data frame of complete id values and strata to achieve correct base n for the situation in which not all subjects experience adverse events. See df_patient_characteristics for an example id_df that pairs with df_adverse_events.
statistic	String indicating the statistics that will be reported. The default is "{n} ({p})"
by_values	Optional vector of complete by values, listed in desired order, to achieve correct table structure for the situation in which an adverse event of a certain grade is not observed for a given soc

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digits

Specifies the number of decimal places to round the summary statistics. By default integers are shown to zero decimal places, and percentages are formatted with $style_percent()$. If you would like to modify either of these, pass a vector of integers indicating the number of decimal places to round the statistics. For example, if the statistic being calculated is "{n} ({p}%)" and you want the percent rounded to 2 decimal places use digits = c(0, 2). User may also pass a styling function: digits = $style_sigfig$

sort

Controls order of AEs and SOCs in output table. The default is NULL, where AEs and SOCs are sorted alphanumerically (and factors sorted according to their factor level). Use sort = "ae" to sort AEs in decreasing frequency order, sort = "soc" to sort SOCs in decreasing order, and sort = c("ae", "soc") to sort both. AEs are sorted within SOC.

zero_symbol

String used to represent cells with zero counts. Default is the em-dash ("\U2014"). Using zero_symbol = NULL will print the zero count statistics, e.g. "0 (0)"

missing_location

location where the column summarizing values with missing levels by= will be located in the final table. Must be one of c("first", "last", "hide). Default is "first"

Value

```
a 'tbl_ae' object
```

Example Output

```
# Example 1 ------
tbl_ae_ex1 <-
 df_adverse_events %>%
 tbl_ae(
  id = patient_id,
  ae = adverse_event,
  soc = system_organ_class,
  by = grade,
  strata = trt
 modify_header(all_ae_cols() ~ "**Grade {by}**")
# Example 2 ------
tbl_ae_ex2 <-
 df_adverse_events %>%
 tbl_ae(
  id = patient_id,
  ae = adverse_event,
  by = grade
 ) %>%
```

tbl_ae_count

```
modify\_header(all\_ae\_cols() ~ "**Grade \{by\}**")
```

tbl_ae_count

Tabulate Raw AE Counts

Description

Create a table counting all AEs.

Usage

```
tbl_ae_count(
  data,
  ae,
  soc = NULL,
  by = NULL,
  strata = NULL,
  by_values = NULL,
  digits = NULL,
  sort = NULL,
  zero_symbol = "\U2014",
  missing_location = c("first", "last", "hide")
)
```

data	Data frame
ae	Variable name of the adverse event column
soc	Variable name of the system organ class column
by	Variable to split results by, e.g. report AEs by grade
strata	Variable to stratify results by, e.g. report AEs summaries by treatment group
by_values	Optional vector of complete by values, listed in desired order, to achieve correct table structure for the situation in which an adverse event of a certain grade is not observed for a given soc
digits	Specifies the number of decimal places to round the summary statistics. By default integers are shown to zero decimal places, and percentages are formatted with $style_percent()$. If you would like to modify either of these, pass a vector of integers indicating the number of decimal places to round the statistics. For example, if the statistic being calculated is "{n} ({p}%)" and you want the percent rounded to 2 decimal places use digits = $c(0, 2)$. User may also pass a styling function: digits = $style_sigfig$
sort	Controls order of AEs and SOCs in output table. The default is NULL, where AEs and SOCs are sorted alphanumerically (and factors sorted according to their factor level). Use sort = "ae" to sort AEs in decreasing frequency order, sort = "soc" to sort SOCs in decreasing order, and sort = c("ae", "soc") to sort both. AEs are sorted within SOC.

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zero_symbol

String used to represent cells with zero counts. Default is the em-dash ("\U2014"). Using zero_symbol = NULL will print the zero count statistics, e.g. "0 (0)"

missing_location

location where the column summarizing values with missing levels by= will be located in the final table. Must be one of c("first", "last", "hide). Default is "first"

Details

tbl_ae_count counts all AEs (whereas tbl_ae counts by maximum grade). Thus, tbl_ae_count does not provide percentages as multiple AEs can be counted per subject.

Value

```
a 'tbl_ae_count' object
```

Example Output

See Also

```
tbl_ae
```

Examples

```
# Example 1 ------
tbl_ae_count_ex1 <-
tbl_ae_count(
   data = df_adverse_events,
   ae = adverse_event,
   soc = system_organ_class,
   strata = trt,
   by = grade
) %>%
modify_header(all_ae_cols() ~ "**Grade {by}**")
```

tbl_ae_focus

Tabulate AE Focused (Dichotomous) Summaries

Description

Summarize dichotomous AE data. For example, report the rate of patients that have an AE of Grade 3 or higher.

tbl_ae_focus

Usage

```
tbl_ae_focus(
  data,
  include,
  id,
  ae,
  soc = NULL,
  strata = NULL,
  label = NULL,
  id_df = NULL,
  statistic = "{n} ({p})",
  digits = NULL,
  sort = NULL,
  zero_symbol = "\U2014"
)
```

data	Data frame
include	Vector of column names to summarize. Column names may be quoted or unquoted. All columns must be class 'logical'.
id	Variable name of the patient ID
ae	Variable name of the adverse event column
SOC	Variable name of the system organ class column
strata	Variable to stratify results by, e.g. report AEs summaries by treatment group
label	A named list of labels that will be applied in the resulting table. Names must be those passed in include=. Default is NULL, and either the label attribute or the column name will be used.
id_df	Optional data frame of complete id values and strata to achieve correct base n for the situation in which not all subjects experience adverse events. See df_patient_characteristics for an example id_df that pairs with df_adverse_events.
statistic	String indicating the statistics that will be reported. The default is "{n} ({p})"
digits	Specifies the number of decimal places to round the summary statistics. By default integers are shown to zero decimal places, and percentages are formatted with $style_percent()$. If you would like to modify either of these, pass a vector of integers indicating the number of decimal places to round the statistics. For example, if the statistic being calculated is "{n} ({p}%)" and you want the percent rounded to 2 decimal places use digits = $c(0, 2)$. User may also pass a styling function: digits = $style_sigfig$
sort	Controls order of AEs and SOCs in output table. The default is NULL, where AEs and SOCs are sorted alphanumerically (and factors sorted according to their factor level). Use sort = "ae" to sort AEs in decreasing frequency order, sort = "soc" to sort SOCs in decreasing order, and sort = c("ae", "soc") to sort both. AEs are sorted within SOC.
zero_symbol	String used to represent cells with zero counts. Default is the em-dash ("\U2014"). Using zero_symbol = NULL will print the zero count statistics, e.g. "0 (0)"

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Value

```
a 'tbl_ae_focus' object
```

Example Output

Examples

tbl_listing

Data Listing Table

Description

Function creates a gtsummary-class listing of data. Column labels are used as column headers, when present. The listing prints observations in the order of the input data.

Usage

```
tbl_listing(data, group_by = NULL, bold_headers = TRUE)
```

Arguments

data a data frame

group_by Single variable name indicating a grouping variable. Default is NULL for no

grouping variable. When specified, a grouping row will be added to the first

column. See details below.

bold_headers logical indicating whether to bold column headers. Default is TRUE

Value

gtsummary data listing

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group_by

The grouping column and the first column in the table will be combined and the type/class may be converted to common type/class for both columns. However, if either the group_by= column or the first column are factors, the factor column(s) will first be converted to character.

The groups are ordered according to the grouping variable's type (i.e., character, numeric, or factor).

Details

The purpose of tbl_listing() is to add support for printing data frames, while taking advantage of the {gtsummary} defaults, e.g. ability to print to most output formats, using print themes to have a common style to all tables in a document, etc.

While the output of tbl_listing() is class 'gtsummary', these tables are not meant to be merged with other 'gtsummary' tables with tbl_merge(), or reporting table contents with inline_text(). The reason is that a proper 'gtsummary' contains additional, hidden structure not present in the result of tbl_listing(). If you do need to report the results of tbl_listing() in-line, it's recommended to convert the table to a data frame, then extract the needed cell, e.g.

```
tbl_listing() |>
  as_tibble(col_names = FALSE) |>
  dplyr::slice(1) |>
  dplyr::pull(colname)`
```

Example Output

```
library(dplyr, warn.conflicts = FALSE)

tbl_listing_ex1 <-
    head(df_adverse_events, n = 10) %>%
    select(system_organ_class, adverse_event, grade, drug_attribution, patient_id) %>%
    arrange(adverse_event, desc(grade)) %>%
    tbl_listing(group_by = system_organ_class) %>%
    bold_labels()

set.seed(11234)
tbl_listing_ex2 <-
df_patient_characteristics %>%
    dplyr::slice_sample(n = 10) %>%
    select(patient_id, status, discontinued, off_trt_ae) %>%
    tbl_listing() %>%
    as_gt() %>%
    gt::opt_row_striping()
```

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tbl_reg_summary

Data Summary Table

Description

Function wraps gtsummary::tbl_summary() to create a data summary table often seen in regulatory submissions. Continuous variable summaries are shown on multiple lines with additional summary statistics and percentages are shown for categorical variables; precision levels estimated based on values observed.

Usage

```
tbl_reg_summary(
  data,
  by = NULL,
  label = NULL,
  statistic = NULL,
  digits = NULL,
  type = NULL,
  value = NULL,
  missing = c("no", "yes", "ifany"),
  missing_text = NULL,
  sort = NULL,
  percent = NULL,
  include = everything()
)
```

data	A data frame
by	A column name (quoted or unquoted) in data. Summary statistics will be calculated separately for each level of the by variable (e.g. by = trt). If NULL, summary statistics are calculated using all observations.
label	List of formulas specifying variables labels, e.g. list(age ~ "Age", stage ~ "Path T Stage"). If a variable's label is not specified here, the label attribute (attr(data\$age, "label")) is used. If attribute label is NULL, the variable name will be used.
statistic	List of formulas specifying types of summary statistics to display for each variable.
digits	List of formulas specifying the number of decimal places to round summary statistics. If not specified, tbl_summary guesses an appropriate number of decimals to round statistics. When multiple statistics are displayed for a single variable, supply a vector rather than an integer. For example, if the statistic being calculated is "{mean} ({sd})" and you want the mean rounded to 1 decimal place, and the SD to 2 use digits = list(age $\sim c(1, 2)$). User may also pass a styling function: digits = age \sim style_sigfig

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List of formulas specifying variable types. Accepted values are c("continuous", type "continuous2", "categorical", "dichotomous"), e.g. type = list(age ~ "continuous", female ~ "dichotomous"). If type not specified for a variable, the function will default to an appropriate summary type. value List of formulas specifying the value to display for dichotomous variables. gtsummary selectors, e.g. all_dichotomous(), cannot be used with this argument. Indicates whether to include counts of NA values in the table. Allowed values missing are "no" (never display NA values), "ifany" (only display if any NA values), and "always" (includes NA count row for all variables). Default is "ifany". String to display for count of missing observations. Default is "Unknown". missing_text List of formulas specifying the type of sorting to perform for categorical data. sort Options are frequency where results are sorted in descending order of frequency and alphanumeric, e.g. sort = list(everything() ~ "frequency") Indicates the type of percentage to return. Must be one of "column", "row", or percent

"cell". Default is "column".

include variables to include in the summary table. Default is everything()

Value

```
a 'tbl_reg_summary' object
```

Example Output

See Also

```
See gtsummary::tbl_summary() help file
See vignette for detailed tutorial
```

```
tbl_reg_summary_ex1 <-
 df_patient_characteristics %>%
 tbl_reg_summary(by = trt, include = c(marker, status))
```

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