

Package ‘cardinalfda’

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Type Package

Title FDA Safety Tables and Figures

Version 0.2.0

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Description Provides implementations of safety tables and figures recommended by the FDA (U.S. Food and Drug Administration) for clinical trial reporting. Functions generate standard outputs for adverse events, laboratory abnormalities, vital signs, exposure, and other safety domains following the FDA's Safety Reporting guidelines. Outputs are built on the 'gtsummary', 'cards', and 'cardx' frameworks, enabling reproducible and submission-ready clinical trial safety summaries.

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URL <https://github.com/pharmaverse/cardinal/>,
<https://pharmaverse.github.io/cardinal/>

BugReports <https://github.com/pharmaverse/cardinal/issues>

Depends R (>= 4.2), cards (>= 0.8.1), cardx (>= 0.3.4), gtsummary (>= 2.5.1)

Imports dplyr (>= 1.2.1)

Suggests cowplot (>= 1.2.0), crane (>= 0.3.1), forcats (>= 1.0.1), ggplot2 (>= 4.0), ggsurvfit (>= 1.2.0), gt (>= 1.3.0), knitr (>= 1.50), labelled (>= 2.16.0), lubridate (>= 1.9), pharmaverseadam (>= 1.3.0), purrr (>= 1.2), random.cdisc.data (>= 0.3.16), rlang (>= 1.1.7), rtables (>= 0.6.11), tern (>= 0.9.8), svglite (>= 2.2.2), testthat (>= 3.3.1), tidyr (>= 1.3.1), withr (>= 3.0.2)

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make_table_02	<i>FDA Table 2: Baseline Demographic and Clinical Characteristics, Safety Population, Pooled Analyses</i>
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Description

Creates FDA Table 2 showing baseline demographic and clinical characteristics for the safety population.

Usage

```
make_table_02(
  df,
  return_ard = TRUE,
  arm_var = "TRT01A",
  saffl_var = "SAFFL",
  vars = c("SEX", "AGE", "AGEGR1", "ETHNIC", "RACE"),
  label = list()
)
```

Arguments

<code>df</code>	(data.frame) dataset (typically ADSL) required to build the table.
<code>return_ard</code>	(flag) whether an ARD should be returned. Defaults to TRUE.
<code>arm_var</code>	(character) name of the treatment arm variable used to split table into columns. Defaults to "TRT01A".
<code>saffl_var</code>	(character) name of the safety flag variable. Defaults to "SAFFL".
<code>vars</code>	(character) variables from df to include in the table. Defaults to c("SEX", "AGE", "AGEGR1", "ETHNIC", "RACE").
<code>label</code>	(named list) variable labels passed to gtsummary::tbl_summary(). Defaults to list().

Details

- df must contain the variables specified by arm_var, saffl_var, and all variables in vars.
- Rows with saffl_var != "Y" are excluded from the table (safety population filter applied internally).
- Data-specific preprocessing (e.g. joining additional variables, deriving new columns) should be performed by the caller before passing df to this function.
- Continuous variables are summarised with mean (SD) and median (min, max).
- Categorical variables are summarised with n (%).
- When return_ard = TRUE, returns a named list with elements table (a gtsummary object) and ard (the intermediate ARD); otherwise returns the gtsummary table directly.

Value

A gtsummary table, or if return_ard = TRUE, a named list with elements table and ard.

Examples

```
library(dplyr)

adsl <- pharmaverseadam::adsl |>
  filter(TRT01A != "Screen Failure")

result <- make_table_02(df = adsl)
result$table
```

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