

Package ‘ProAE’

April 9, 2021

Type Package

Title PRO-CTCAE Data Management, Analysis, and Graphical Tools

Version 0.1.2

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Description A collection of tools to facilitate standardized analysis and graphical procedures when using the National Cancer Institute’s Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE).

License GPL-3

Encoding UTF-8

LazyData true

Imports ggplot2, ggnewscale, ggtext, dplyr, Hmisc, magrittr, ExactCIDiff, DescTools

Suggests knitr, rmarkdown

VignetteBuilder knitr

Depends R (>= 3.6.0)

RoxygenNote 7.1.1

NeedsCompilation no

Repository CRAN

Date/Publication 2021-04-09 20:50:03 UTC

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ProAE	<i>ProAE.</i>
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Description

This package is a collection of tools for analyzing and plotting PRO-CTCAE data

PROCTCAE_table	<i>PRO-CTCAE variable / label crosswalk</i>
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Description

A crosswalk / look-up table of expected variable names for associated PRO-CTCAE symptom items.

Format

A data frame with 124 rows and 2 variables

Details

- name. Expected variable name - item number/letter corresponds to the NCI-PRO-CTCAE (English) Item Library Version 1.0
- short_label. Item label including the item symptom group and frequency, severity, interference, or presence component

Author(s)

Blake Langlais

References

<https://healthcaredelivery.cancer.gov/pro-ctcae/instrument-pro.html>

toxFigures	<i>Create PRO-CTCAE severity frequency distribution figures for individual survey items and composite scores</i>
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Description

Data format should be in 'long' format, where each PRO-CTCAE item is a variable/column.

Usage

```
toxFigures(
  dsn,
  id_var,
  cycle_var,
  baseline_val,
  arm_var = NA,
  plot_limit = NA,
  colors = 1,
  label = 0,
  summary_only = FALSE,
  cycles_only = FALSE,
  x_lab_angle = 0,
  x_lab_vjust = 1,
  x_lab_hjust = 0,
  x_label = "Randomized Treatment Assignment",
  plot_data = FALSE
)
```

Arguments

dsn	A data.frame object with PRO-CTCAE data
id_var	A character string. Name of ID variable differentiating each PRO-CTCAE survey/participant entered as a quoted string.
cycle_var	A character string. Name of variable differentiating one longitudinal/repeated PRO-CTCAE survey from another, within an individual ID.
baseline_val	A number indicating the expected baseline cycle/time point.
arm_var	A character string. Name of arm variable differentiating treatment groups. Must be character or factor class. Overall frequencies will be reported if no arm/grouping variable is provided. Defaults to NA.
plot_limit	A number. Limit the number of cycles to be plotted up to and including a given cycle number. All available cycle time points are plotted if no cycle number is provided. Defaults to NA.
colors	A number. Specify the coloring scheme of symptom grades within frequency bars. Options include: 1 = Blue and red color shading, 2 = qualitative color shades (color blind friendly), 3 = black and white. Defaults to 1.

label	A number. Label frequency bars with sample size (n) or percent shown on the y-axis. Label options include: 1 = sample size (n) within each cycle (symptom grade 0 or higher), 2 = sample size (n) within each cycle with present symptoms (symptom grade > 0), 3 = sample size (n) within each cycle with severe symptoms (symptom grade >= 3), 4 = percent of subjects (symptoms (symptom grade > 0), 5 = percent of subjects within each cycle with severe symptoms (symptom grade >= 3). No labels will be applied if not specified. Defaults to NA.
summary_only	Logical. Only display the summary measures in figures / Suppress the individual time points from plotting. Defaults to FALSE.
cycles_only	Logical. Only display the longitudinal time points in figures / Suppress the summary measures from plotting. Defaults to FALSE.
x_lab_angle	A integer between 0 and 360. Allows the user to rotate the x axis labels in order to fit long arm names (0 or 45 recommended). Defaults to 0.
x_lab_vjust	A number. A ggplot2 object option. Allows the user to vertically adjusts the x axis labels in order to fit arm names. Defaults to 1.
x_lab_hjust	A number. A ggplot2 object option. Allows the user to horizontally adjusts the x axis labels in order to fit arm names. Defaults to 0.
x_label	A character string. Label for the x axis of the plot. Defaults to "Randomized Treatment Assignment" if arm_var is specified, defaults to "Overall" if not arm_var is specified.
plot_data	Logical. Return the data used to construct plots as element of the returned object. Defaults to FALSE.

Value

A list object. The returned object is a (k X 2) or (k x 3) nested list. Where k is the number of PRO-CTCAE item groups (e.g. pain, fatigue, nausea); list[[1 ... i ... k]]. For each list item there are 2 or 3 elements. The 1st element of each list item is the name of the PRO-CTCAE item group returned as a string. The 2nd element is the PRO-CTCAE figure as a ggplot object. The 3rd (and optional) element is the data used to construct the ggplot figure, available via plot_data.

Examples

```
# --- Simulate example PRO-CTCAE data
fig_acute = toxFigures(dsn = ProAE::tox_acute,
  cycle_var = "Cycle",
  baseline_val = 1,
  arm_var = "arm",
  id_var = "id",
  label = 0,
  x_lab_angle = -45,
  x_lab_vjust = .3,
  x_lab_hjust = .2,
  colors = 2)
fig_acute[[1]]
```

toxScores	<i>Re-code PRO-CTCAE text responses, apply a zero-imputation procedure, and construct PRO-CTCAE composite grades.</i>
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Description

This function takes in a data frame set with PRO-CTCAE survey text fields/responses and returns a data frame with appropriate numerical re-coding. This function will accept 1 or up to all 124 PRO-CTCAE survey fields. All PRO-CTCAE variable names MUST conform to a pre-specified naming structure. PRO-CTCAE variable names are made up of FOUR components: 1) 'PROCTCAE', 2) number [1,2,3, ..., i, ..., 80], 3) 'A', 'B', or 'C' component of the i-th PRO-CTCAE field, 4) and 'SCL' (if severity, interference, or frequency) or 'IND' (if yes/no variable). Each component must be delimited by an underscore (_)

Usage

```
toxScores(
  dsn,
  reformat = FALSE,
  impute = FALSE,
  composites = FALSE,
  short_labels = FALSE
)
```

Arguments

dsn	A data.frame object with PRO-CTCAE data
reformat	Reformat PRO-CTCAE text responses to numeric scores. Defaults to FALSE.
impute	Apply zero-imputation where appropriate. Defaults to FALSE.
composites	Construct composite grade using available PRO-CTCAE variables within dsn. Defaults to FALSE.
short_labels	Add PRO-CTCAE short labels to available PRO-CTCAE variables within returned object

Details

- [EX1] Question 1 of PRO-CTCAE should be: PROCTCAE_1A_SCL
- [EX2] Question 48 of PRO-CTCAE should be: PROCTCAE_48A_SCL, PROCTCAE_48B_SCL, PROCTCAE_48C_SCL
- [EX3] Question 73 of PRO-CTCAE should be: PROCTCAE_73A_IND

This function also constructs PRO-CTCAE composite grades. Composite grade variables for respective PRO-CTCAE item groups are created and named as PROCTCAE_##_COMP.

1. https://healthcaresdelivery.cancer.gov/pro-ctcae/pro-ctcae_english.pdf

2. Ethan Basch, et al. Development of a Composite Scoring Algorithm for the National Cancer Institute's Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE). ISOQOL 2019
3. Basch E, et al. Composite Grading Algorithm for the National Cancer Institute's Patient-Reported Outcomes version of the Common Terminology Criteria for Adverse Events (PRO-CTCAE). Clinical Trials 2020.

Data format should be in 'long' format, where each PRO-CTCAE item is a variable/column.

Value

A data.frame object.

Examples

```
tox_acute_comp = toxScores(dsn = ProAE::tox_acute, composites = TRUE)
```

toxTables	<i>Create toxicity tables for individual and composite PRO-CTCAE survey items.</i>
-----------	--

Description

Data format should be in 'long' format, where each PRO-CTCAE item is a variable/column.

Usage

```
toxTables(
  dsn,
  id_var,
  cycle_var,
  baseline_val,
  type = "bl_adjusted",
  test = "c",
  riskdiff = FALSE,
  risk_ci = "wald",
  risk_ci_alpha = 0.05,
  arm_var = NA,
  cycle_limit = NA
)
```

Arguments

dsn	A data.frame object with PRO-CTCAE data.
id_var	A character string. Name of ID variable differentiating each PRO-CTCAE survey/participant entered as a quoted string.

cycle_var	A character string. Name of variable differentiating one longitudinal/repeated. PRO-CTCAE survey from another, within an individual ID.
baseline_val	A number indicating the expected baseline cycle/time point.
type	A character string. Type of summary measure to be used. Options include: "max_post_bl" = Use subjects' maximum score post-baseline visit. "bl_adjusted" = Use subjects' baseline adjusted score over the study period. The baseline adjusted score is derived by the following: If the maximum score post-baseline is more severe than the baseline score, then the use maximum score post-baseline is used as the adjusted score. Otherwise, if the maximum score post-baseline is the same or less severe than the baseline score, then zero (0) is used as the adjusted score. Defaults to "bl_adjusted".
test	A character string. Specify the statistical test to apply where comparing rates among arms. Options include: "c" = chi square, "f" = fisher's exact. Defaults to "c".
riskdiff	Logical. Calculates risk differences between two arms. Valid if there are only two arms in the data.frame specified. This option will countermand options called with the test parameter. Defaults to FALSE.
risk_ci	A character string. Specify the confidence interval type to be constructed for risk differences. Options include: "wald", "agresti-caffo", "exact". Defaults to wald. Please note: exact confidence intervals are computationally intensive and will likely take considerable time and memory to compute.
risk_ci_alpha	A number between 0 and 1. Specify the alpha level of the risk difference confidence intervals. Defaults to 0.05.
arm_var	A character string. Name of arm variable differentiating treatment groups. Must be character or factor class. Overall frequencies will be reported if no arm/grouping variable is provided. Defaults to NA.
cycle_limit	A number. Limit the data to be analyzed up to and including a given cycle number or time point. Defaults to NA.

Value

A list object with data.frame elements for individual items and composite grades.

Examples

```
toxTables(dsn=ProAE::tox_acute, id_var="id", cycle_var="Cycle", baseline_val=1)
```

tox_acute

PRO-CTCAE data reflecting acute drug toxicity

Description

Simulated example data where the drug group experiences acute toxicity followed by symptom abatement over the course of treatment.

Format

A data frame with 1400 rows and 5 variables

Details

- id. Subject identifier
- Cycle. Time variable denoting visits/cycles (1-10)
- arm. Treatment groups include drug and placebo
- PROCTCAE_78A_SC. PRO-CTCAE frequency item for nosebleeds
- PROCTCAE_78B_SC. PRO-CTCAE severity item for nosebleeds

Author(s)

Blake Langlais

tox_chronic

PRO-CTCAE data reflecting chronic drug toxicity

Description

Simulated example data where the drug group experiences chronic toxicity over the course of treatment.

Format

A data frame with 1400 rows and 5 variables

Details

- id. Subject identifier
- Cycle. Time variable denoting visits/cycles (1-10)
- arm. Treatment groups include drug and placebo
- PROCTCAE_78A_SC. PRO-CTCAE frequency item for nosebleeds
- PROCTCAE_78B_SC. PRO-CTCAE severity item for nosebleeds

Author(s)

Blake Langlais

tox_cumulative	<i>PRO-CTCAE data reflecting cumulative drug toxicity</i>
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Description

Simulated example data where drug toxicity is cumulative over the course of treatment.

Format

A data frame with 1400 rows and 5 variables

Details

- id. Subject identifier
- Cycle. Time variable denoting visits/cycles (1-10)
- arm. Treatment groups include drug and placebo
- PROCTCAE_78A_SC. PRO-CTCAE frequency item for nosebleeds
- PROCTCAE_78B_SC. PRO-CTCAE severity item for nosebleeds

Author(s)

Blake Langlais

tox_cyclic	<i>PRO-CTCAE data reflecting cyclical drug toxicity</i>
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Description

Simulated example data where the drug group experiences cyclicly toxicity post-treatment administration

Format

A data frame with 1400 rows and 5 variables

Details

- id. Subject identifier
- Cycle. Time variable denoting visits/cycles (1-10)
- arm. Treatment groups include drug and placebo
- PROCTCAE_78A_SC. PRO-CTCAE frequency item for nosebleeds
- PROCTCAE_78B_SC. PRO-CTCAE severity item for nosebleeds

Author(s)

Blake Langlais

tox_late

PRO-CTCAE data reflecting late incipient drug toxicity

Description

Simulated example data where the drug group experiences late incipient toxicity towards the end of the treatment period.

Format

A data frame with 1400 rows and 5 variables

Details

- id. Subject identifier
- Cycle. Time variable denoting visits/cycles (1-10)
- arm. Treatment groups include drug and placebo
- PROCTCAE_78A_SC. PRO-CTCAE frequency item for nosebleeds
- PROCTCAE_78B_SC. PRO-CTCAE severity item for nosebleeds

Author(s)

Blake Langlais

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