

Package ‘volcanoPlot’

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Type Package

Title Volcano Plot for Clinical Trial Adverse Events

Version 1.0.0

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Description

Interactive adverse event (AE) volcano plot for monitoring clinical trial safety. This tool allows users to view the overall distribution of AEs in a clinical trial using standard (e.g. MedDRA preferred term) or custom (e.g. Gender) categories using a volcano plot similar to proposal by Zink et al. (2013) <[doi:10.1177/1740774513485311](https://doi.org/10.1177/1740774513485311)>. This tool provides a stand-alone shiny application and flexible shiny modules allowing this tool to be used as a part of more robust safety monitoring framework like the Shiny app from the 'safetyGraphics' R package.

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Imports fmsb, dplyr, DT, ggplot2, tidyverse, purrr

Suggests safetyGraphics, safetyData

NeedsCompilation no

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getStats	<i>Get Summary AE Statistics</i>
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Description

Compares reference and comparison groups to calculate group-wise metrics and p-values for use in AE volcano plot.

Usage

```
getStats(dfAE, dfDemog, settings, stat = "Risk Ratio")
```

Arguments

<code>dfAE</code>	Adverse events dataset structured as 1 record per adverse event per subject
<code>dfDemog</code>	Subject-level dataset
<code>settings</code>	Named list of settings (see examples below for standard list)
<code>stat</code>	Statistic to calculate for AE plot. Options are risk ratio ("RR" or "Risk Ratio"), risk difference ("RD" or "Risk Difference"). Defaults to "Risk Ratio".

Value

a data frame of group-wise statistics for use in the volcano plot

Examples

```
settings<-list(
  stratification_col="AEBODSYS",
  group_col="ARM",
  reference_group="Placebo",
  comparison_group="Xanomeline High Dose",
  id_col="USUBJID"
)
getStats(dfAE=safetyData::adam_adae, dfDemog = safetyData::adam_adsl, settings)
```

volcanoApp*Volcano App*

Description

Initializes stand-alone volcano plot shiny application.

Usage

```
volcanoApp(  
  dfAE = safetyData::adam_adae,  
  dfDemog = safetyData::adam_ads1,  
  settings = NULL,  
  runNow = TRUE  
)
```

Arguments

dfAE	AE Data
dfDemog	demog data
settings	safetyGraphics settings
runNow	run app immediately?

Value

Initializes Shiny app. No return value.

volcanoPlot*Create a volcano plot*

Description

Creates a paneled volcano plot showing the distribution of Adverse events. Options to highlight selected events and customize options are provided.

Usage

```
volcanoPlot(data, highlights = c(), ...)
```

Arguments

data	A data frame from getStats()
highlights	A list providing a column and values to be highlighted in the chart
...	Extra options to change the look of the plot. ‘fillcol = c(‘sienna2’, ‘skyblue2’, ‘grey’)’: fill colors; ‘pcutoff = 0.05’: p value cutoff; ‘ecutoff = 1’: estimate cutoff, ‘GroupLabels = c(‘Comparison Group’, ‘Reference Group’)’: custom group labels.

Value

a volcano plot created with ggplot

Examples

```
settings<-list(
  stratification_col="AEBODSYS",
  group_col="ARM",
  reference_group="Placebo",
  comparison_group="Xanomeline High Dose",
  id_col="USUBJID"
)
stats<-getStats(dfAE=safetyData::adam_adae, dfDemog = safetyData::adam_adsl, settings)
volcanoPlot(stats)
```

volcano_server

Volcano Plot Module - Server

Description

Modularized server for AE volcano plot.

Usage

```
volcano_server(input, output, session, params)
```

Arguments

input	module input
output	module output
session	module session
params	parameters object with ‘data’ and ‘settings’ options.

Value

returns shiny module Server function

`volcano_ui`

Volcano Plot Module - UI

Description

Modularized user interface for AE Volcano plot

Usage

`volcano_ui(id)`

Arguments

`id` module id

Value

returns shiny module UI

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