

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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Encoding UTF-8

RoxygenNote 7.2.3

Imports fmsb, dplyr, DT, ggplot2, tidyr, shiny, purrr

Suggests safetyGraphics, safetyData

NeedsCompilation no

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Contents

getStats	2
volcanoApp	3
volcanoPlot	3
volcano_server	4
volcano_ui	5

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

dfAE	Adverse events dataset structured as 1 record per adverse event per subject
dfDemog	Subject-level dataset
settings	Named list of settings (see examples below for standard list)
stat	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	<i>Volcano App</i>
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Description

Initializes stand-alone volcano plot shiny application.

Usage

```
volcanoApp(  
  dfAE = safetyData::adam_adae,  
  dfDemog = safetyData::adam_adsl,  
  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	<i>Create a volcano plot</i>
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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	<i>Volcano Plot Module - UI</i>
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Description

Modularized user interface for AE Volcano plot

Usage

```
volcano_ui(id)
```

Arguments

id	module id
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Value

returns shiny module UI

Index

`getStats`, [2](#)

`volcano_server`, [4](#)

`volcano_ui`, [5](#)

`volcanoApp`, [3](#)

`volcanoPlot`, [3](#)