Package ‘vaxpmx’

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Type Package

Title Vaccines Pharmacometrics

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Description Estimate vaccine efficacy (VE) using immunogenicity data.
The inclusion of immunogenicity data in regression models can increase precision in VE. The methods are described in the publications ``Elucidating vaccine efficacy using a correlate of protection, demographics, and logistic regression'' and ``Improving precision of vaccine efficacy evaluation using immune correlate data in time-to-event models'' by Julie Dudasova, Zdenek Valenta, and Jeffrey R. Sachs (2024).

License GPL-3

Encoding UTF-8

LazyData true

RoxygenNote 7.3.2

Imports methods (>= 3.5.2), stats, MASS (>= 7.3-51.6), dplyr (>= 1.0.0), survival (>= 3.2-11)

Suggests knitr, rmarkdown, testthat

NeedsCompilation no

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`coxphParametricSampling` *Accounting for the uncertainty on the fitted "coxph" model and observed data*

Description

`coxphParametricSampling` is used for vaccine efficacy confidence interval construction. It provides a vector of vaccine efficacy values, with length of `nboot`. 95% confidence interval, defined by 2.5th and 97.5th quantile of this vector, accounts for the uncertainty on the model fit (via parametric resampling of the posterior distribution of the model parameters) and observed data (via bootstrapping).

Usage

```
coxphParametricSampling(Fit, nboot = 2000, Data.vaccinated, Data.control)
```

Arguments

`Fit`	an object of class inheriting from "coxph" representing the fitted model
`nboot`	a numeric value for number of bootstrap samples for confidence interval construction
`Data.vaccinated`	a data frame for the vaccinated group, containing the variables in the fitted model
`Data.control`	a data frame for the control group, containing the variables in the fitted model

Value

a vector of vaccine efficacy values `VE_set`, with length of `nboot`

Examples

```
# Load required packages
library(dplyr)
library(survival)

# Load an example dataset
data(data_temp)
Data.vaccinated <- filter(data_temp, vaccine == 1)
Data.control <- filter(data_temp, vaccine == 0)

# Fit Cox proportional hazards model relating neutralizing titer
```

```
# to time to disease or end of follow-up
coxFit <- coxph(Surv(time_event, disease_any) ~ nAb1, data = data_temp)

# Estimate 95\% confidence interval of vaccine efficacy based on the fitted model
efficacySet <- coxphParametricSampling(coxFit, nboot = 500, Data.vaccinated, Data.control)
CI <- lapply(EfficacyCI(efficacySet),"*", 100)
```

`data_temp` *Example of a hypothetical vaccine clinical trial data set*

Description

A dataset containing immunogenicity data, and clinical outcome data in the vaccinated and control groups. The dataset is provided in the form of a data frame.

Usage

```
data_temp
```

Format

Data frame:

ID identification of subjects

nAb1 value of neutralizing titer for serotype 1

nAb2 value of neutralizing titer for serotype 2

group binary indicator of a baseline demographic characteristics of interest

vaccine binary indicator of treatment arm, with value 1 in vaccinated and 0 in control subjects

type_disease serotype of disease

disease_any binary indicator of disease caused by any serotype

time_event time to disease or end of follow-up in days

`EfficacyCI` *Efficacy summary (mean, median, confidence intervals)*

Description

Function summarizes efficacy statistics (mean, median, confidence intervals) based on the set of estimated efficacy values and chosen condfidence interval.

Usage

```
EfficacyCI(efficacySet, ci = 0.95)
```

Arguments

`efficacySet`	numeric vector - vector of estimated efficacy values
`ci`	numeric - required confidence level

Details

Confidence intervals are calculated using quantiles of estimated efficacy values.

Value

named list - mean, median, CILow, CIHigh

Examples

```
# Load required packages
library(dplyr)

# Load an example dataset
data(data_temp)
Data.vaccinated <- filter(data_temp, vaccine == 1)
Data.control <- filter(data_temp, vaccine == 0)

# Fit logistic model relating neutralizing titer to disease status
logisticFit <- glm(disease_any ~ nAb1, data = data_temp, family = binomial())

# Estimate 95\% confidence interval of vaccine efficacy based on the fitted model
efficacySet <- glmParametricSampling(logisticFit, nboot = 500, Data.vaccinated, Data.control)
EfficacyCI(efficacySet)
```

`glmParametricSampling` *Accounting for the uncertainty on the fitted "`glm`" model and observed data*

Description

`glmParametricSampling` is used for vaccine efficacy confidence interval construction. It provides a vector of vaccine efficacy values, with length of `nboot`. 95% confidence interval, defined by 2.5th and 97.5th percentile of this vector, accounts for the uncertainty on the model fit (via parametric resampling of the posterior distribution of the model parameters) and observed data (via bootstrapping).

Usage

```
glmParametricSampling(Fit, nboot = 2000, Data.vaccinated, Data.control)
```

Arguments

`Fit`	an object of class inheriting from `"glm"` representing the fitted model
`nboot`	a numeric value for number of bootstrap samples for confidence interval construction
`Data.vaccinated`	a data frame for the vaccinated group, containing the variables in the fitted model; data must include a column called "vaccine" with binary indicator of vaccination status
`Data.control`	a data frame for the control group, containing the variables in the fitted model; data must include a column called "vaccine" with binary indicator of vaccination status

Value

a vector of vaccine efficacy values `VE_set`, with length of `nboot`

Examples

```
# Load required packages
library(dplyr)

# Load an example dataset
data(data_temp)
Data.vaccinated <- filter(data_temp, vaccine == 1)
Data.control <- filter(data_temp, vaccine == 0)

# Fit logistic model relating neutralizing titer to disease status
logisticFit <- glm(disease_any ~ nAb1, data = data_temp, family = binomial())

# Estimate 95\% confidence interval of vaccine efficacy based on the fitted model
efficacySet <- glmParametricSampling(logisticFit, nboot = 500, Data.vaccinated, Data.control)
CI <- lapply(EfficacyCI(efficacySet),"*", 100)
```

`vaxpmx` *vaxpmx*

Description

pharmacometric modeling in vaccines

Author(s)

Julie Dudasova

`ve` *Vaccine efficacy estimation*

Description

Calculates vaccine efficacy and confidence interval as described in Dudasova et al., 2024, BMC Med Res Methodol and Dudasova et al., 2024, NPJ Vaccines

Usage

```
ve(Fit, Data, nboot = 2000)
```

Arguments

`Fit`	an object of class inheriting from `"glm"` or `"coxph"` representing the fitted model
`Data`	a data frame containing the variables in the fitted model; data must include a column called "vaccine" with binary indicator of vaccination status
`nboot`	a numeric value for number of bootstrap samples for confidence interval construction

Value

a value of vaccine efficacy `VE` and lower and upper bound of confidence interval `CI`

Examples

```
#' # Load required packages
library(survival)

# Load an example dataset
data(data_temp)

# Fit logistic model relating neutralizing titer to disease status
logisticFit <- glm(disease_any ~ nAb1, data = data_temp, family = binomial())

# Fit Cox proportional hazards model relating neutralizing titer
# to time to disease or end of follow-up
coxFit <- coxph(Surv(time_event, disease_any) ~ nAb1, data = data_temp)

# Estimate vaccine efficacy and 95\% confidence interval based on the fitted models
ve(logisticFit, data_temp, nboot = 500)
ve(coxFit, data_temp, nboot = 500)
```

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