

Package ‘OneArmTTE’

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Type Package

Title One-Arm Clinical Trial Designs for Time-to-Event Endpoint

Version 1.0

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Description Get operating characteristics of one-arm clinical trial designs for time-to-event endpoint through simulation and perform analysis with time-to-event data.

Imports tibble, dplyr, tidyr, survival

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License GPL-3

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`cumhazard`*Get Cumulative Hazard at a Landmark Timepoint*

Description

Get Cumulative Hazard at a Landmark Timepoint

Usage

```
cumhazard(  
  eventRates = tibble::tibble(duration = c(3, 100), rate = c(log(2)/5, log(2)/5 * 0.5)),  
  landmark  
)
```

Arguments

`eventRates` A tibble containing period duration (`duration`) and event rate (`rate`) for specified periods.

`landmark` The landmark of interest to evaluate cumulative hazard.

Value

A numeric which is the cumulative hazard at a landmark timepoint.

Examples

```
# Piecewise exponential event rates of 0.5 for time 0-3, 0.4 for time 3-6, and 0.5 after  
cumhaz <- cumhazard(eventRates=tibble::tibble(duration = c(3,3,100),rate = c(0.5, 0.4, 0.3)),  
  landmark=12)
```

`example_data`*An Example Trial Dataset*

Description

A dataset containing the time-to-event information. The variables are as follows

Usage

```
data(example_data)
```

Format

A data frame with 3 variables and 200 observations

Details

- time. event or censoring time
- censor. censoring indicator; 1=event
- Trt. treatment arm name

OneArmTTEAnalysis	<i>Perform analysis on the data of one-arm clinical trial with time-to-event endpoint</i>
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Description

This function can get analysis results on the input trial data using several approaches for one-arm trial design with time-to-event endpoint. Default approaches include one-sample log-rank test, Landmark Kaplan-Meier method and binary method which regards the survival of each subject at a landmark is a binary variable. In addition, if RWdata is not NULL, the RWdata input will be used as an external control and cox model will be used to evaluate the treatment effect of input trial data (experimental arm) compared with the external control.

Usage

```
OneArmTTEAnalysis(
  data,
  eventRates.ctrl,
  landmark,
  RWdata = NULL,
  RWSurvCal = FALSE,
  conf.type = "plain",
  alpha = 0.05
)
```

Arguments

data	Trial data. A tibble/data.frame containing time and censor, where censor=1 indicates event.
eventRates.ctrl	Event rates of historical control.
landmark	The landmark of interest to evaluate the survival rate for Landmark Kaplan-Meier method and binary method.
RWdata	The real world data to be used as external control; A tibble/data.frame containing time and censor, where censor=1 indicates event; default is NULL.
RWSurvCal	Indicator of whether to calculate historical cumulative hazard and survival rate at landmark from real world data; default is FALSE.
conf.type	Type of confidence interval in the survival model; One of "none", "plain" (the default), "log", "log-log", "logit" or "arcsin".
alpha	Type I error rate level.

Details

This function outputs a list of analysis results of each design, including: 1) p-value of one-sample log-rank test, 2) historical survival rate at landmark, 3) survival rate estimate with confidence interval of landmark kaplan-meier method, 4) survival rate estimate with confidence interval of binary method, 5) p-value of binary method, 6) hazard ratio estimate with confidence interval compared with real world data (if available), 7) p-value of log-rank test compared with real world data (if available).

Value

No visible return values.

Examples

```
library(survival)
data(example_data)
# Piecewise exponential of historical control
median.ctrl <- c(14.3, 1.5, 4.9)
eventRates.ctrl <- tibble::tibble(duration=c(4,2,100),rate=log(2)/median.ctrl)
OneArmTTEAnalysis(example_data, eventRates.ctrl, landmark=6)
```

OneArmTTEDesign	<i>Get operating characteristics of one-arm clinical trial design with time-to-event endpoint</i>
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Description

Using simulation, this function can get operating characteristics of several approaches for one-arm trial design with time-to-event endpoint. Default approaches include one-sample log-rank test, Landmark Kaplan-Meier method and binary method which regards the survival of each subject at a landmark is a binary variable. In addition, if RWdata is not NULL, the RWdata input will be used as an external control and cox model will be used to evaluate the treatment effect of simulated data (experimental arm) compared with the external control. The output includes probability of rejecting null hypothesis of each design, average number of events at analysis, and average analysis time after last patient in. When eventRates is same as eventRates.ctrl, the probability of rejecting null hypothesis is type I error; When eventRates is the alternative hypothesis from desirable treatment effect, the probability of rejecting null hypothesis is power.

Usage

```
OneArmTTEDesign(
  n,
  eventRates.ctrl,
  eventRates,
  enrollRates,
  dropoutRates,
```

```

    cutTime,
    landmark,
    Event = FALSE,
    n.event,
    RWdata = NULL,
    RWSurvCal = FALSE,
    conf.type = "plain",
    alpha = 0.05,
    nsim = 10000,
    seed = 43
  )

```

Arguments

n	Number of subjects.
eventRates.ctrl	Event rates of historical control.
eventRates	Event rates of subjects in the trial.
enrollRates	Enrollment rates of subjects in the trial.
dropoutRates	Dropout rates of the subjects in the trial.
cutTime	Analysis time after last patient in; not used if Event=TRUE.
landmark	The landmark of interest to evaluate the survival rate for Landmark Kaplan-Meier method.
Event	Indicator of whether the analysis is driven by number of events; default is FALSE.
n.event	Number of events at analysis; not used if Event=FALSE.
RWdata	The real world data to be used as external control; A tibble/data.frame containing time and censor, where censor=1 indicates event; default is NULL.
RWSurvCal	Indicator of whether to calculate historical cumulative hazard and survival rate at landmark from real world data as the null case; default is FALSE.
conf.type	Type of confidence interval in the survival model; One of "none", "plain" (the default), "log", "log-log", "logit" or "arcsin".
alpha	Type I error rate level.
nsim	Number of simulations; default is 10000.
seed	Seed for simulation.

Details

The function output a list of the operating characteristics including: 1) probability of rejecting null hypothesis of each design, 2) average number of events at analysis, 3) average analysis time after last patient in.

Value

No visible return values.

Examples

```

library(survival)
# Piecewise exponential of historical control
median.ctrl <- c(14.3, 1.5, 4.9)
eventRates.ctrl <- tibble::tibble(duration=c(4,2,100),rate=log(2)/median.ctrl)
# Piecewise exponential assumption of treatment:
# Hazard ratio = 1 for time 0-3 and Hazard ratio = 0.47 after
eventRates.trt = tibble::tibble(duration=c(3,1,2,100),rate=log(2)/c(14.3, median.ctrl/0.47))
# Constant enrollment rates and dropout rates
enrollRates = tibble::tibble(duration=106, rate=14/3)
dropoutRates = tibble::tibble(duration=106, rate=0.2/12)
OneArmTTEDesign(n=40, eventRates.ctrl, eventRates.trt, enrollRates, dropoutRates, cutTime=3,
                landmark=6, Event=FALSE, conf.type = 'plain', alpha=0.05, nsim=100, seed=43)

```

rpwenroll

Generate Piecewise Exponential Enrollment

Description

Generate Piecewise Exponential Enrollment

Usage

```
rpwenroll(n = NULL, enrollRates = tibble(duration = c(1, 2), rate = c(2, 5)))
```

Arguments

n	Number of observations. Default of NULL yields random enrollment size.
enrollRates	A tibble containing period duration (duration) and enrollment rate (rate) for specified enrollment periods. If necessary, last period will be extended to ensure enrollment of specified n.

Value

A vector of random enrollment times following piecewise exponential distribution.

Examples

```

# piecewise uniform (piecewise exponential inter-arrival times) for 10k patients enrollment
# enrollment rates of 5 for time 0-100, 15 for 100-300, and 30 thereafter
x <- rpwenroll(n=10000, enrollRates=tibble::tibble(rate = c(5, 15, 30), duration = c(100,200,100)))
plot(x,1:10000,
     main="Piecewise uniform enrollment simulation",xlab="Time",
     ylab="Enrollment")
# exponential enrollment
x <- rpwenroll(10000, enrollRates=tibble::tibble(rate = .03, duration = 1))
plot(x,1:10000,main="Simulated exponential inter-arrival times",
     xlab="Time",ylab="Enrollment")

```

Description

The piecewise exponential distribution allows a simple method to specify a distribution where the hazard rate changes over time. It is likely to be useful for conditions where failure rates change, but also for simulations where there may be a delayed treatment effect or a treatment effect that is otherwise changing (e.g., decreasing) over time. `rpwexp()` is to support simulation of both the Lachin and Foulkes (1986) sample size method for (fixed trial duration) as well as the Kim and Tsatis(1990) method (fixed enrollment rates and either fixed enrollment duration or fixed minimum follow-up).

Usage

```
rpwexp(n = 100, failRates = tibble(duration = c(1, 1), rate = c(10, 20)))
```

Arguments

<code>n</code>	Number of observations to be generated.
<code>failRates</code>	A tibble containing duration and rate variables. <code>rate</code> specifies failure rates during the corresponding interval duration specified in <code>duration</code> . The final interval is extended to be infinite to ensure all observations are generated.

Details

Using the `cumulative=TRUE` option, enrollment times that piecewise constant over time can be generated.

Value

A vector of random event times following piecewise exponential distribution.

Examples

```
# get 10k piecewise exponential failure times
# failure rates are 1 for time 0-.5, 3 for time .5 - 1 and 10 for >1.
# intervals specifies duration of each failure rate interval
# with the final interval running to infinity
x <- rpwexp(10000, failRates=tibble::tibble(rate = c(1, 3, 10), duration = c(.5,.5,1)))
plot(sort(x),(10000:1)/10001,log="y", main="PW Exponential simulated survival curve",
      xlab="Time",ylab="P{Survival}")
# exponential failure times
x <- rpwexp(10000, failRates=tibble::tibble(rate = 5, duration=1))

plot(sort(x),(10000:1)/10001,log="y", main="Exponential simulated survival curve",
      xlab="Time",ylab="P{Survival}")
```

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