

Package ‘ClinTrialPredict’

May 7, 2026

Title Predicting and Simulating Clinical Trial with Time-to-Event Endpoint

Version 0.0.4

Description Predict the course of clinical trial with a time-to-event endpoint for both two-arm and single-arm design. Each of the four primary study design parameters (the expected number of observed events, the number of subjects enrolled, the observation time, and the censoring parameter) can be derived analytically given the other three parameters. And the simulation datasets can be generated based on the design settings.

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Encoding UTF-8

RoxygenNote 7.3.2

Suggests knitr, rmarkdown, testthat (>= 3.0.0), R.rsp

Config/testthat/edition 3

VignetteBuilder R.rsp

NeedsCompilation no

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Repository CRAN

Date/Publication 2024-11-25 11:40:18 UTC

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| | |
|-----------------|--|
| CensRate.OneArm | <i>Calculate the censoring rate for a one-arm design</i> |
|-----------------|--|

Description

Calculate the censoring rate for a one-arm design

Usage

```
CensRate.OneArm(
  N = NULL,
  d = NULL,
  s = NULL,
  m = NULL,
  l = NULL,
  alpha = NULL,
  nu = NULL
)
```

Arguments

| | |
|-------|--|
| N | Number of subjects plan to enrolled |
| d | expected number of events observed at time l |
| s | enrollment period |
| m | maximum follow-up for a single subject |
| l | observation time |
| alpha | shape parameter of weibull survival distribution |
| nu | scale parameter of weibull survival distribution |

Value

This function returns a list containing all design parameters, including the calculated censoring rate gamma.

Examples

```
CensRate.OneArm(N=100, d=10, l=10, s=12, m=6, alpha=1, nu=20)
```

CensTime.TwoArm *Calculate the censoring rate for a two-arm clinical trial*

Description

Calculate the censoring rate for a two-arm clinical trial

Usage

```
CensTime.TwoArm(
  N.0 = NULL,
  N.1 = NULL,
  d = NULL,
  l = NULL,
  alpha0.t = NULL,
  nu0.t = NULL,
  alpha1.t = NULL,
  nu1.t = NULL,
  s = NULL,
  m = NULL,
  design2 = NULL
)
```

Arguments

| | |
|----------|--|
| N.0 | number of subjects plan to be enrolled in control arm |
| N.1 | number of subjects plan to be enrolled in experimental arm |
| d | expected number of events observed at time l |
| l | observation time |
| alpha0.t | shape parameter of weibull survival distribution for control arm |
| nu0.t | scale parameter of weibull survival distribution for control arm |
| alpha1.t | shape parameters of weibull survival distribution for experimental arm |
| nu1.t | scale parameter of a weibull survival distribution for control arm |
| s | enrollment time |
| m | maximum follow-up time for a subject |
| design2 | a list containing all the above parameters for two-arm design |

Value

This function returns a list containing all design parameters, including the calculated censoring rate `gamma.c`

Examples

```
#calculate the censoring parameter
CensTime.TwoArm(N.0=100,N.1=100,d=10,l=3,alpha0.t=1,nu0.t=5,alpha1.t=2,nu1.t=4,s=5,m=4)
```

NumEventsSub.OneArm *Calculate the expected number of events or number of subjects enrolled in a one-arm clinical trial*

Description

Calculate the expected number of events or number of subjects enrolled in a one-arm clinical trial

Usage

```
NumEventsSub.OneArm(
  N = NULL,
  d = NULL,
  l = NULL,
  gamma = NULL,
  s = NULL,
  m = NULL,
  alpha = NULL,
  nu = NULL,
  design1 = NULL
)
```

Arguments

| | |
|---------|---|
| N | Number of subjects plan to enrolled |
| d | expected number of events observed at time l |
| l | observation time |
| gamma | parameter of the exponential distribution of censoring time |
| s | enrollment period |
| m | maximum follow-up for a single subject |
| alpha | shape parameter of weibull survival distribution |
| nu | scale parameter of weibull survival distribution |
| design1 | a list containing all the above parameters for one-arm design |

Value

This function returns a list containing all design parameters as the same with input parameters of this function.

Examples

```
# Calculate the expected number of events in a one-arm clinical trial
NumEventsSub.OneArm(N=100,d=NULL,l=3,gamma=0.1,s=12,m=6,alpha=1,nu=20)
```

| | |
|---------------------|---|
| NumEventsSub.TwoArm | <i>Calculate the expected number of events or number of subjects enrolled in a two-arm clinical trial</i> |
|---------------------|---|

Description

Calculate the expected number of events or number of subjects enrolled in a two-arm clinical trial

Usage

```
NumEventsSub.TwoArm(  
  N.0 = NULL,  
  N.1 = NULL,  
  ratio = NULL,  
  d = NULL,  
  l = NULL,  
  gamma.c = NULL,  
  alpha0.t = NULL,  
  nu0.t = NULL,  
  alpha1.t = NULL,  
  nu1.t = NULL,  
  s = NULL,  
  m = NULL,  
  design2 = NULL  
)
```

Arguments

| | |
|----------|--|
| N.0 | number of subjects plan to be enrolled in control arm |
| N.1 | number of subjects plan to be enrolled in experimental arm |
| ratio | randomization ratio between two arms: $N.1 / N.0$ |
| d | expected number of events observed at time l |
| l | observation time |
| gamma.c | parameter of the exponential distribution of censoring time |
| alpha0.t | shape parameter of weibull survival distribution for control arm |
| nu0.t | scale parameter of weibull survival distribution for control arm |
| alpha1.t | shape parameters of weibull survival distribution for experimental arm |
| nu1.t | scale parameter of a weibull survival distribution for control arm |
| s | enrollment time |
| m | maximum follow-up time for a subject |
| design2 | a list containing all the above parameters for two-arm design |

Value

This function returns a list containing all design parameters as the same with input parameters of this function.

Examples

```
# calculate the expected number of events
NumEventsSub.TwoArm(N.0=100,N.1=100,l=6,gamma.c=1,alpha0.t = 1,nu0.t=5,alpha1.t=2,nu1.t=4,s=5,m=4)

# calculate the expected number of events using a list as input
design2 <- list(N.0=100,N.1=100,l=6,gamma.c=1,alpha0.t = 1,nu0.t=5,alpha1.t=2,nu1.t=4,s=5,m=4)
NumEventsSub.TwoArm(design2=design2)

# calculate the number of subject enrolled
NumEventsSub.TwoArm(ratio=1,d=24,l=6,gamma.c=1,alpha0.t = 1,nu0.t=5,alpha1.t=2,nu1.t=4,s=5,m=4)
```

 ObsTime.OneArm

Calculate the observation time for a one-arm clinical trial

Description

Calculate the observation time for a one-arm clinical trial

Usage

```
ObsTime.OneArm(
  N = NULL,
  d = NULL,
  s = NULL,
  m = NULL,
  alpha = NULL,
  nu = NULL,
  gamma = NULL
)
```

Arguments

| | |
|-------|---|
| N | Number of subjects plan to enrolled |
| d | expected number of events observed at time l |
| s | enrollment period |
| m | maximum follow-up for a single subject |
| alpha | shape parameter of weibull survival distribution |
| nu | scale parameter of weibull survival distribution |
| gamma | parameter of the exponential distribution of censoring time |

Value

This function returns a list containing all design parameters, including the calculated observation time l .

Examples

```
ObsTime.OneArm(N=100, d=10, gamma=0.1, s=12, m=6, alpha=1, nu=20)
```

```
ObsTime.TwoArm          Calculate the observation time for a two-arm clinical trial
```

Description

predicting two-arm clinical trial

Usage

```
ObsTime.TwoArm(  
  N.0 = NULL,  
  N.1 = NULL,  
  ratio = NULL,  
  d = NULL,  
  gamma.c = NULL,  
  alpha0.t = NULL,  
  nu0.t,  
  alpha1.t,  
  nu1.t,  
  s,  
  m,  
  design2 = NULL  
)
```

Arguments

| | |
|----------|--|
| N.0 | number of subjects plan to be enrolled in control arm |
| N.1 | number of subjects plan to be enrolled in experimental arm |
| ratio | randomization ratio between two arms: $N.1 / N.0$ |
| d | expected number of events observed at time l |
| gamma.c | parameter of the exponential distribution of censoring time |
| alpha0.t | shape parameter of weibull survival distribution for control arm |
| nu0.t | scale parameter of weibull survival distribution for control arm |
| alpha1.t | shape parameters of weibull survival distribution for experimental arm |
| nu1.t | scale parameter of a weibull survival distribution for control arm |
| s | enrollment time |
| m | maximum follow-up time for a subject |
| design2 | a list containing all the above parameters for two-arm design |

Value

This function returns a list containing all design parameters, including the calculated observation time l

Examples

```
# calculate the observation time
ObsTime.TwoArm(N.0=100,N.1=100,d=10,gamma.c=1,alpha0.t = 1,nu0.t=5,alpha1.t=2,nu1.t=4,s=5,m=4)
```

SimData.OneArm

Simulating survival dataset for a one-arm design

Description

Simulating survival dataset for a one-arm design

Usage

```
SimData.OneArm(
  N = NULL,
  d = NULL,
  l = NULL,
  gamma = NULL,
  s = NULL,
  m = NULL,
  alpha = NULL,
  nu = NULL,
  design1,
  seed,
  nsim
)
```

Arguments

| | |
|---------|---|
| N | Number of subjects plan to enrolled |
| d | expected number of events observed at time l |
| l | observation time |
| gamma | parameter of the exponential distribution of censoring time |
| s | enrollment period |
| m | maximum follow-up for a single subject |
| alpha | shape parameter of weibull survival distribution |
| nu | scale parameter of weibull survival distribution |
| design1 | a list containing all the above parameters for one-arm design |
| seed | random seed number |
| nsim | number of simulations |

Value

This function will return the simulated datasets and the according design settings

Examples

```
design1 <- TrialPred.OneArm(N=100,d=NULL,l=3,gamma=0.1
                          ,s=12,m=6,alpha=1,nu=20)
# Simulate 100 datasets under design1
SimData.OneArm(design1=design1,seed=1234,nsim=100)
```

| | |
|----------------|---|
| SimData.TwoArm | <i>Simulating survival dataset for a two-arm design</i> |
|----------------|---|

Description

Simulating survival dataset for a two-arm design

Usage

```
SimData.TwoArm(
  N.0 = NULL,
  N.1 = NULL,
  ratio = NULL,
  d = NULL,
  l = NULL,
  gamma.c = NULL,
  s = NULL,
  m = NULL,
  alpha0.t = NULL,
  nu0.t = NULL,
  HR = NULL,
  alpha1.t = NULL,
  nu1.t = NULL,
  design2 = NULL,
  seed = NULL,
  nsim = NULL
)
```

Arguments

| | |
|-------|--|
| N.0 | number of subjects plan to be enrolled in control arm |
| N.1 | number of subjects plan to be enrolled in experimental arm |
| ratio | randomization ratio between two arms: N.1 / N.0 |
| d | expected number of events observed at time l |
| l | observation time |

| | |
|----------|--|
| gamma.c | parameter of the exponential distribution of censoring time |
| s | enrollment time |
| m | maximum follow-up time for a subject |
| alpha0.t | shape parameter of weibull survival distribution for control arm |
| nu0.t | scale parameter of weibull survival distribution for control arm |
| HR | hazard ratio of experimental group over control group |
| alpha1.t | shape parameters of weibull survival distribution for experimental arm |
| nu1.t | scale parameter of a weibull survival distribution for control arm |
| design2 | a list containing all the above parameters for two-arm design |
| seed | random seed |
| nsim | number of simulations |

Value

This function will return the simulated datasets and the according design settings

Examples

```
design2 <- NumEventsSub.TwoArm(N.0=100,N.1=100,l=6,gamma.c=1
                             ,alpha0.t = 1,nu0.t=5,alpha1.t=2,nu1.t=4,s=5,m=4)
SimData.TwoArm(design2=design2,seed=1234,nsim=100)
```

TrialPred.OneArm *Function for predicting one-arm clinical trial*

Description

Function for predicting one-arm clinical trial

Usage

```
TrialPred.OneArm(
  N = NULL,
  d = NULL,
  l = NULL,
  gamma = NULL,
  s = NULL,
  m = NULL,
  alpha = NULL,
  nu = NULL,
  design1 = NULL
)
```

Arguments

| | |
|---------|---|
| N | Number of subjects plan to enrolled |
| d | expected number of events observed at time l |
| l | observation time |
| gamma | parameter of the exponential distribution of censoring time |
| s | enrollment period |
| m | maximum follow-up for a single subject |
| alpha | shape parameter of weibull survival distribution |
| nu | scale parameter of weibull survival distribution |
| design1 | a list containing all the above parameters for one-arm design |

Value

This function returns a list containing all design parameters as the same with input parameters of this function. If any one of the parameters d, N, l or gamma is missing, it can be calculated based on the other parameters.

Examples

```
# Calculate the expected number of events in a one-arm clinical trial
TrialPred.OneArm(N=100,d=NULL,l=3,gamma=0.1,s=12,m=6,alpha=1,nu=20)

#Calculate the expected number of events using a list as input
design1 <- list(N=100,d=NULL,l=3,gamma=0.1,s=12,m=6,alpha=1,nu=20)
TrialPred.OneArm(design1=design1)

#Calculate the number of subjects enrolled
TrialPred.OneArm(N=NULL,d=8,l=15,gamma=0.1,s=12,m=6,alpha=1,nu=20)

#Calculate the observation time
TrialPred.OneArm(N=100,d=10,l=NULL,gamma=0.1,s=12,m=6,alpha=1,nu=20)

#Calculate the censoring parameter gamma
TrialPred.OneArm(N=100,d=10,l=10,gamma=NULL,s=12,m=6,alpha=1,nu=20)
```

TrialPred.TwoArm

Function for predicting two-arm clinical trial

Description

predicting two-arm clinical trial

Usage

```

TrialPred.TwoArm(
  N.0 = NULL,
  N.1 = NULL,
  ratio = NULL,
  d = NULL,
  l = NULL,
  gamma.c = NULL,
  alpha0.t = NULL,
  nu0.t = NULL,
  HR = NULL,
  alpha1.t = NULL,
  nu1.t = NULL,
  s = NULL,
  m = NULL,
  design2 = NULL
)

```

Arguments

| | |
|----------|--|
| N.0 | number of subjects plan to be enrolled in control arm |
| N.1 | number of subjects plan to be enrolled in experimental arm |
| ratio | randomization ratio between two arms: $N.1 / N.0$ |
| d | expected number of events observed at time l |
| l | observation time |
| gamma.c | parameter of the exponential distribution of censoring time |
| alpha0.t | shape parameter of weibull survival distribution for control arm |
| nu0.t | scale parameter of weibull survival distribution for control arm |
| HR | hazard ratio of experimental group over control group |
| alpha1.t | shape parameters of weibull survival distribution for experimental arm |
| nu1.t | scale parameter of a weibull survival distribution for control arm |
| s | enrollment time |
| m | maximum follow-up time for a subject |
| design2 | a list containing all the above parameters for two-arm design |

Value

This function returns a list containing all design parameters as the same with input parameters of this function. If any one of the parameters d, N.0(or N.1), l or gamma.c is missing, it can be calculated based on the other parameters.

Examples

```
# calculate the expected number of events
TrialPred.TwoArm(N.0=100,N.1=100,d=NULL,l=6,gamma.c=1
                 ,alpha0.t = 1,nu0.t=5,alpha1.t=2,nu1.t=4,s=5,m=4)

# calculate the expected number of events using a list as input
design2 <- list(N.0=100,N.1=100,d=NULL,l=6,gamma.c=1
              ,alpha0.t = 1,nu0.t=5,alpha1.t=2,nu1.t=4,s=5,m=4)
TrialPred.TwoArm(design2=design2)

# calculate the number of subject enrolled
TrialPred.TwoArm(N.0=NULL,N.1=NULL,ratio=1,d=24,l=6,gamma.c=1
                 ,alpha0.t = 1,nu0.t=5,alpha1.t=2,nu1.t=4,s=5,m=4)

# calculate the observation time
TrialPred.TwoArm(N.0=100,N.1=100,d=10,l=NULL,gamma.c=1
                 ,alpha0.t = 1,nu0.t=5,alpha1.t=2,nu1.t=4,s=5,m=4)

# calculate the censoring parameter
TrialPred.TwoArm(N.0=100,N.1=100,d=10,l=3,gamma.c=NULL
                 ,alpha0.t=1,nu0.t=5,alpha1.t=2,nu1.t=4,s=5,m=4)
```

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