Package 'ClinTrialPredict'

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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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Contents

`CensRate.OneArm` *Calculate the censoring rate for a one-arm design*

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

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 expeTrcted 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 *Simulating survival dataset for a two-arm design*

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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