Package: SSRMST (via r-universe)

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Type Package

Title Sample Size Calculation using Restricted Mean Survival Time

Description Calculates the power and sample size based on the
difference in Restricted Mean Survival Time.

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Depends R (>= 3.4.0)

Imports survival, survRM2

License GPL-2

NeedsCompilation no

RoxygenNote 6.0.1

Suggests knitr, rmarkdown

VignetteBuilder knitr

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Repository https://mikihoriguchi.r-universe.dev

RemoteUrl https://github.com/cran/SSRMST

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Description

The difference in restricted mean survival time (RMST), a clinically interpretable model-free measure, can be one of the alternatives to the hazard ratio. The package calculates the study sample size and power in designing clinical trials using the difference in RMST. Two types of one-sided tests, non-inferiority and superiority tests, are prepared.

Details

Please check the vignette for details: browseVignettes(package = "SSRMST")

Author(s)

Miki Horiguchi, Hajime Uno

References

Uno H, Claggett B, Tian L, Inoue E, Gallo P, Miyata T, Schrag D, Takeuchi M, Uyama Y, Zhao L, Skali H, Solomon S, Jacobus S, Hughes M, Packer M, Wei LJ. Moving beyond the hazard ratio in quantifying the between-group difference in survival analysis. Journal of clinical Oncology 2014, 32, 2380-2385.

Uno H, Wittes J, Fu H, Solomon SD, Claggett B, Tian L, Cai T, Pfeffer MA, Evans SR, Wei LJ. Alternatives to Hazard Ratios for Comparing the Efficacy or Safety of Therapies in non-inferiority Studies. Annals of Internal Medicine 2015, 163, 127-134.

See Also

survival survRM2

Examples

```
#---Example data

ac_rate   = 15
ac_period = 35
tot_time  = 510
tau       = 500
scale0    = 8500
scale1    = 8500
margin    = 18

a = ssrmst(ac_rate=ac_rate, ac_period=ac_period, tot_time=tot_time,
           tau=tau, scale0=scale0, scale1=scale1, margin=margin, ntest=20)
print(a)
```

---

print.ssrmst	*print.ssrmst*

Description

S3 method for class 'ssrmst'

Usage

```
## S3 method for class 'ssrmst'
print(x, ...)
```

Arguments

x	Object to be printed.
...	Further arguments ignored in this function.

---

ssrmst	*Sample Size Calculation using Restricted Mean Survival Time*

Description

The package calculates the study sample size and power in designing clinical trials using the difference in restricted mean survival time (RMST). Two types of one-sided tests, non-inferiority and superiority tests, are prepared. Under certain conditions, 2,000 sets of realizations in default are generated for calculating confidence intervals of RMST differences. Then the power is calculated, i.e., the chance that the lower bound of 2,000 confidence intervals of RMST differences falls above a margin.

Usage

```
ssrmst(ac_rate=NULL, ac_period=NULL, ac_number=NULL, tot_time, tau,
       shape0=1, scale0, shape1=1, scale1, margin=0, allocation1=0.5,
       one_sided_alpha=0.025, seed=NULL, ntest=2000)
```

Arguments

ac_rate	Accrual rate: the number of patients per unit time.
ac_period	Accrual period: the time point at last accrual.
ac_number	Accrual number: the total number of accrual patients.
tot_time	Total study time: the time point at last follow-up.
tau	Truncation time point to calculate RMSTs.
shape0, shape1	Shape parameters for the Weibull distribution in both the control (arm0) and the treatment (arm1).

scale0, scale1	Scale parameters for the Weibull distribution in both the control (arm0) and the treatment (arm1). Note that when the PH assumption is assumed, the value of the scale parameter in the treatment (arm1) needs to be larger than or equal to that in the control (arm0), because the difference of the RMSTs (arm1 minus arm0) is of interest.
margin	Non-inferiority margin: a clinically acceptable difference in RMST. A value of minus margin is used to evaluate the power. When default (margin = 0), a superiority test is selected.
allocation1	Proportion of patients allocated to the treatment (arm1). Default value is 0.5.
one_sided_alpha	
	Nominal type I error level as one-sided. When default (one_sided_alpha = 0.025), 0.95 confidence intervals of the difference in RMST are estimated to calculate the power.
seed	Random seed used for the sampling. Default is NULL.
ntest	Number of iterations. When default (ntest = 2000), 2,000 sets of realizations are generated for calculating confidence intervals of RMST differences.

Details

For more details, please refer to the vignette: browseVignettes(package = "SSRMST")

Value

A list with components:

result	Total study population and expected number of events.
power1	The power based on separate variance, i.e., the chance that the lower bound of 2,000 confidence intervals of difference in RMST falls above a value of minus margin in a non-inferiority test (or above 0 in a superiority test).
power2	The power based on pooled variance, i.e., the chance that the lower bound of 2,000 confidence intervals of difference in RMST falls above a value of minus margin in a non-inferiority test (or above 0 in a superiority test).
ac_rate	Accrual rate used in the analyses.
ac_period	Accrual period used in the analyses.
ac_number	Accrual number used in the analyses.
ac_type	Accrual type: 1; the number of patients per unit time is automatically calculated by specifying the parameters (ac_rate and ac_period), 2; the accrual rate is automatically calculated by specifying the parameters (ac_period and ac_number), 3; the accrual period is automatically calculated by specifying the parameters (ac_rate and ac_number).
tot_time	Total study time used in the analyses.
margin	Margin used in the analyses.
tau	Truncation time point used in the analyses.
one_sided_alpha	
	Nominal type I error level as one-sided used in the analyses.
note	Note regarding the truncation time, tau.

References

Uno H, Wittes J, Fu H, Solomon SD, Claggett B, Tian L, Cai T, Pfeffer MA, Evans SR, Wei LJ. Alternatives to Hazard Ratios for Comparing the Efficacy or Safety of Therapies in non-inferiority Studies. Annals of Internal Medicine 2015, 163, 127-134.

See Also

survival survRM2

Examples

```
#---Example data

#--Non-inferiority test
ac_rate   = 15
ac_period = 35
tot_time  = 510
tau       = 500
scale0    = 8500
scale1    = 8500
margin    = 18

a = ssrmst(ac_rate=ac_rate, ac_period=ac_period, tot_time=tot_time,
           tau=tau, scale0=scale0, scale1=scale1, margin=margin, ntest=20)
print(a)


#--Superiority test
ac_rate   = 15
ac_period = 35
tot_time  = 510
tau       = 500
scale0    = 4000
scale1    = 8500
b = ssrmst(ac_rate=ac_rate, ac_period=ac_period, tot_time=tot_time,
           tau=tau, scale0=scale0, scale1=scale1, ntest=20)
print(b)
```

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