

Package ‘rashnu’

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Title Balanced Sample Size and Power Calculation Tools

Version 0.1.1

Description Implements sample size and power calculation methods with a focus on balance and fairness in study design, inspired by the Zoroastrian deity Rashnu, the judge who weighs truth. Supports survival analysis and various hypothesis testing frameworks.

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Encoding UTF-8

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Imports shiny, DT, stats

Suggests covr, testthat (>= 3.0.0)

Config/testthat/edition 3

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<https://github.com/zarathucorp/rashnu>

BugReports <https://github.com/zarathucorp/rashnu/issues>

NeedsCompilation no

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lakatosSampleSize

Sample Size Calculation Using Lakatos Method for Survival Analysis

Description

Computes the required sample size and expected event numbers for two-group survival analysis using Lakatos' method under exponential survival assumptions and varying weight functions (log-rank, Gehan, Tarone-Ware).

Usage

```
lakatosSampleSize(
  syear,
  yrsurv1,
  yrsurv2,
  alloc,
  accrualTime,
  followTime,
  alpha,
  power,
  method = c("logrank", "gehan", "tarone-ware"),
  side = c("two.sided", "one.sided"),
  b = 24
)
```

Arguments

syear	Survival time horizon in years.
yrsurv1	Survival probability of the standard group at syear.
yrsurv2	Survival probability of the test group at syear.
alloc	Allocation ratio (Test / Standard). For equal allocation, use 1.
accrualTime	Accrual period duration.
followTime	Additional follow-up time after last patient is accrued.
alpha	Significance level (e.g., 0.05 for two-sided tests).
power	Desired statistical power (e.g., 0.8).
method	Weighting method for test statistic. One of "logrank", "gehan", or "tarone-ware".
side	Type of test: "two.sided" or "one.sided".
b	Number of time divisions per year for numerical integration (default = 24).

Value

A list containing:

Sample_size_of_standard_group Required sample size in the standard group.

Sample_size_of_test_group Required sample size in the test group.

Total_sample_size Total sample size.

Expected_event_numbers_of_standard_group Expected number of events in the standard group.

Expected_event_numbers_of_test_group Expected number of events in the test group.

Total_expected_event_numbers Total number of expected events.

Actual_power Achieved power given the calculated sample size.

error (Optional) Error message when sample size cannot be calculated.

References

Lakatos E. (1988). Sample sizes based on the log-rank statistic in complex clinical trials. *Biometrics*, 44, 229–241.

Lakatos E, Lan KK. (1992). A comparison of sample size methods for the logrank statistic. *Statistics in Medicine*, 11(2), 179–191.

Web calculator (Superiority): <https://nshi.jp/en/js/twosurvyr/>

Examples

```
lakatosSampleSize(  
  syear = 2,  
  yrsurv1 = 0.7,  
  yrsurv2 = 0.6,  
  alloc = 1,  
  accrualTime = 1,  
  followTime = 1,  
  alpha = 0.05,  
  power = 0.8,  
  method = "logrank",  
  side = "two.sided"  
)
```

Description

Calculates the required sample size or power for a single-arm survival study using various transformation-based methods, including arcsine-square root, log-log, logit, and others. This function assumes an exponential survival model.

Usage

```

oneSurvSampleSize(
  survTime,
  p1,
  p2,
  accrualTime,
  followTime,
  alpha,
  power,
  side = c("two.sided", "one.sided"),
  method = c("arcsin", "log-log", "logit", "log", "log-swog", "identity")
)

```

Arguments

survTime	Time point at which survival is evaluated (e.g., median follow-up time).
p1	Expected survival probability under the alternative hypothesis.
p2	Survival probability under the null hypothesis.
accrualTime	Patient accrual period.
followTime	Additional follow-up period after accrual ends.
alpha	Significance level (e.g., 0.05).
power	Desired statistical power (e.g., 0.8).
side	Type of hypothesis test. Either "two.sided" (default) or "one.sided".
method	Transformation method for comparison. One of "arcsin", "log-log", "logit", "log", "log-swog", "identity".

Value

A named numeric vector with:

SampleSize Calculated required sample size.

Power Achieved power with the calculated sample size.

References

Fleming TR, Harrington DP. (1991). *Counting Processes and Survival Analysis*. New York: Wiley, pp. 236–237, Example 6.3.1.

Andersen PK, Borgan O, Gill RD, Keiding N. (1993). *Statistical Models Based on Counting Processes*. New York: Springer-Verlag, pp. 176–287, Section IV.1–3.

Bie O, Borgan O, Liestol K. (1987). Confidence intervals and confidence bands for the cumulative hazard rate function and their small sample properties. *Scandinavian Journal of Statistics*, 14(3), 221–233.

Borgan O, Liestol K. (1990). A note on confidence intervals and bands for the survival function based on transformations. *Scandinavian Journal of Statistics*, 17(1), 35–41.

Nagashima K, Noma H, Sato Y, Gosho M. (2020). Sample size calculations for single-arm survival studies using transformations of the Kaplan–Meier estimator. *Pharmaceutical Statistics*. <https://doi.org/10.1002/pst.2090> Available at: <https://arxiv.org/abs/2012.03355>

Web calculator (One-sample): <https://nshi.jp/en/js/onesurvyr/>

Examples

```
oneSurvSampleSize(  
  survTime = 2,  
  p1 = 0.75,  
  p2 = 0.6,  
  accrualTime = 1,  
  followTime = 1,  
  alpha = 0.05,  
  power = 0.8,  
  side = "two.sided",  
  method = "log-log"  
)
```

rashnuBasic

Interactive Sample Size Calculator for Survival Studies (Shiny App)

Description

Launches a Shiny web application that calculates required sample sizes and expected event numbers for different types of survival analysis designs:

- Two-group Non-Inferiority
- Two-group Superiority (Lakatos method)
- One-sample survival test (with transformation methods)

Usage

```
rashnuBasic()
```

Details

Users can specify survival probabilities, accrual and follow-up durations, allocation ratios, non-inferiority margins, transformation methods, and test types. The app dynamically adjusts input UI based on the selected design and displays results in a data table format.

Test Types:

- "ni" - Non-Inferiority (two-group exponential survival comparison)
- "sup" - Superiority (Lakatos method with logrank/Gehan/Tarone-Ware weighting)
- "one" - One-sample survival test with multiple transformation options

Included References:

- Jung SH, Chow SC. Journal of Biopharmaceutical Statistics, 2012.
- Lakatos E. Biometrics, 1988.
- Lakatos & Lan. Statistics in Medicine, 1992.
- Fleming & Harrington. Counting Processes and Survival Analysis, 1991.
- Borgan O, Andersen PK et al. Springer-Verlag, 1993.
- Nagashima et al. Pharmaceutical Statistics, 2020.

Value

Launches a Shiny app in the default browser.

Note

Requires associated functions `twoSurvSampleSizeNI()`, `lakatosSampleSize()`, and `oneSurvSampleSize()` to be defined in the environment. Assumes a CSS file is available at "www/style.css" for custom styling.

Examples

```
if (interactive()) {
  rashnuBasic()
}
```

<code>twoSurvSampleSizeNI</code>	<i>Sample Size Calculation for Two-Group Non-Inferiority Survival Study</i>
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Description

Calculates the required sample size and expected event numbers for a non-inferiority trial with two survival curves, using piecewise integration of hazard functions under exponential survival assumptions.

Usage

```
twoSurvSampleSizeNI(
  syear,
  yrsurv1,
  yrsurv2,
  alloc,
  accrualTime,
  followTime,
  alpha,
  power,
  margin
)
```

Arguments

syear	Survival time horizon (e.g., median survival time) in years.
yrsurv1	Survival probability of the standard group at syear.
yrsurv2	Survival probability of the test group at syear.
alloc	Allocation ratio (Test / Standard), e.g., 1 means equal allocation.
accrualTime	Duration of patient accrual period.
followTime	Follow-up period after last patient is accrued.
alpha	One-sided significance level (e.g., 0.025).
power	Desired statistical power (e.g., 0.8).
margin	Non-inferiority margin for hazard ratio (HR).

Value

A list containing:

Sample_size_of_standard_group Required sample size in the standard group.

Sample_size_of_test_group Required sample size in the test group.

Total_sample_size Total sample size.

Expected_event_numbers_of_standard_group Expected number of events in the standard group.

Expected_event_numbers_of_test_group Expected number of events in the test group.

Total_expected_event_numbers Total number of expected events across both groups.

References

Jung SH, Chow SC. (2012). On sample size calculation for comparing survival curves under general hypothesis testing. *Journal of Biopharmaceutical Statistics*, 22(3), 485–495.

Web calculator (Non-Inferiority): <https://nshi.jp/en/js/twosurvyrni/>

Examples

```
twoSurvSampleSizeNI(
  syear = 2,
  yrsurv1 = 0.7,
  yrsurv2 = 0.65,
  alloc = 1,
  accrualTime = 1,
  followTime = 1,
  alpha = 0.025,
  power = 0.8,
  margin = 1.3
)
```

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