Package ‘rashnu’

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Title Balanced Sample Size and Power Calculation Tools

Version 0.1.0

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 testthat (>= 3.0.0)

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NeedsCompilation no

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Contents

`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"
)
```

`oneSurvSampleSize` *One-Sample Survival Study Sample Size or Power Calculation*

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 0, 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()
}
```

`twoSurvSampleSizeNI` *Sample Size Calculation for Two-Group Non-Inferiority Survival Study*

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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