Package 'SampleSizeR'

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Type Package

Title Sample Size Calculations for Epidemiological, Clinical, and Diagnostic Studies

Version 0.1.0

Description Provides comprehensive methods for sample size determination for epidemiological studies, clinical trials, diagnostic accuracy studies, and diagnostic agreement studies. The package supports prevalence surveys, cluster prevalence studies, unmatched case-control studies, cohort studies, superiority, non-inferiority, and equivalence clinical trials, diagnostic sensitivity, diagnostic specificity, receiver operating characteristic (ROC) area under the curve (AUC), and diagnostic agreement studies. Functions include optional adjustments for finite population correction, design effect, unequal allocation, anticipated response rate, and dropout. Results are returned as standardized 'SampleSizeR' objects with print, summary, plot, and data frame methods.

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Encoding UTF-8

Depends R (>= 4.2.0)

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Contents

`as.data.frame.SampleSizeR` *Convert SampleSizeR Object to Data Frame*

Description

Convert SampleSizeR Object to Data Frame

Usage

```
## S3 method for class 'SampleSizeR'
as.data.frame(x, row.names = NULL, optional = FALSE, ...)
```

Arguments

`x`	A SampleSizeR object.
`row.names`	NULL.
`optional`	ignored.
`...`	Additional arguments.

Value

Data frame.

---

plot.SampleSizeR *Plot Sample Size Result*

Description

Plot Sample Size Result

Usage

```
## S3 method for class 'SampleSizeR'
plot(x, ...)
```

Arguments

x	A SampleSizeR object.
...	Additional arguments.

Value

ggplot object.

---

print.SampleSizeR *Print Sample Size Result*

Description

Prints a SampleSizeR object in a user-friendly format.

Usage

```
## S3 method for class 'SampleSizeR'
print(x, digits = 2, ...)
```

Arguments

x	A SampleSizeR object.
digits	Number of decimal places.
...	Additional arguments.

Value

Invisible x.

`ss_case_control` *Sample Size for an Unmatched Case-Control Study*

Description

Calculates the required sample size for an unmatched case-control study based on the expected odds ratio, exposure prevalence among controls, desired statistical power and significance level.

Usage

```
ss_case_control(
  odds.ratio,
  p0,
  alpha = 0.05,
  power = 0.8,
  ratio = 1,
  dropout = 0
)
```

Arguments

`odds.ratio`	Expected odds ratio (>0).
`p0`	Expected exposure prevalence among controls (0-1).
`alpha`	Type I error. Default = 0.05.
`power`	Statistical power. Default = 0.80.
`ratio`	Number of controls per case. Default = 1.
`dropout`	Expected dropout/non-response proportion (0-1).

Details

The implementation follows the Kelsey/Fleiss approach and supports unequal control-to-case allocation ratios.

Exposure prevalence among cases is estimated from

$$p_1 = \frac{OR \times p_0}{1 + p_0(OR - 1)}$$

Sample size is then calculated using the Kelsey/Fleiss unmatched case-control formula.

Value

Object of class `SampleSizeR`

References

Kelsey JL, Whittemore AS, Evans AS, Thompson WD. Methods in Observational Epidemiology.

Fleiss JL, Levin B, Paik MC. Statistical Methods for Rates and Proportions.

Schlesselman JJ. Case-Control Studies: Design, Conduct and Analysis.

Examples

```
ss_case_control(
    odds.ratio = 2,
    p0 = 0.20
)

ss_case_control(
    odds.ratio = 3,
    p0 = 0.15,
    ratio = 2
)
```

---

ss_clinical_trial *Sample Size for a Two-Arm Parallel Clinical Trial*

Description

Calculates the required sample size for superiority clinical trials with either continuous or binary outcomes.

Usage

```
ss_clinical_trial(
  outcome = c("continuous", "binary"),
  alpha = 0.05,
  power = 0.8,
  ratio = 1,
  dropout = 0,
  mean1 = NULL,
  mean2 = NULL,
  sd = NULL,
  p1 = NULL,
  p2 = NULL
)
```

Arguments

`outcome`	Character string specifying outcome type. One of `"continuous"` or `"binary"`.
`alpha`	Type I error. Default = 0.05.
`power`	Statistical power. Default = 0.80.

ratio	Allocation ratio (Control : Treatment). Default = 1.
dropout	Expected dropout proportion (0-1).
mean1	Mean of treatment group.
mean2	Mean of control group.
sd	Common standard deviation.
p1	Expected event proportion in treatment group.
p2	Expected event proportion in control group.

Details

Supported outcome types:

- Continuous (difference between two means)
- Binary (difference between two proportions)

Supports unequal allocation ratios.

Value

Object of class `SampleSizeR`

References

Chow SC, Shao J, Wang H. Sample Size Calculations in Clinical Research.

Julious SA. Sample Sizes for Clinical Trials.

Fleiss JL et al. Statistical Methods for Rates and Proportions.

Examples

```
## Continuous endpoint

ss_clinical_trial(
    outcome="continuous",
    mean1=15,
    mean2=12,
    sd=5
)

## Binary endpoint

ss_clinical_trial(
    outcome="binary",
    p1=0.30,
    p2=0.50
)
```

`ss_cohort` *Sample Size for an Unmatched Cohort Study*

Description

Calculates the required sample size for an unmatched cohort study based on the expected risk ratio, incidence among the unexposed group, statistical power and significance level.

Usage

```
ss_cohort(risk.ratio, p0, alpha = 0.05, power = 0.8, ratio = 1, dropout = 0)
```

Arguments

`risk.ratio`	Expected relative risk (>0).
`p0`	Expected incidence (risk) in the unexposed group (0-1).
`alpha`	Type I error. Default = 0.05.
`power`	Statistical power. Default = 0.80.
`ratio`	Number of unexposed subjects per exposed subject. Default = 1.
`dropout`	Expected dropout/non-response proportion (0-1).

Details

Supports unequal exposed:unexposed allocation ratios.

Incidence among the exposed group is estimated as

$$p_1 = RR \times p_0$$

The required sample size is calculated using the Fleiss/Kelsey two-proportion formula.

Value

Object of class `SampleSizeR`

References

Kelsey JL et al. Methods in Observational Epidemiology.

Fleiss JL, Levin B, Paik MC. Statistical Methods for Rates and Proportions.

Chow SC, Shao J, Wang H. Sample Size Calculations in Clinical Research.

Examples

```
ss_cohort(
    risk.ratio = 2,
    p0 = 0.10
)

ss_cohort(
    risk.ratio = 1.8,
    p0 = 0.15,
    ratio = 2
)
```

`ss_diagnostic_agreement` *Sample Size for Diagnostic Agreement Studies*

Description

Estimates the required sample size for testing agreement using Cohen's kappa.

The default implementation ("pearson") is based on the multinomial agreement model and Pearson goodness-of-fit effect size.

This implementation is **not** the original Donner & Eliasziw (1992) sample size method.

Usage

```
ss_diagnostic_agreement(
  kappa1,
  kappa0 = 0.4,
  prevalence = 0.5,
  alpha = 0.05,
  power = 0.8,
  response.rate = 1,
  dropout = 0,
  method = c("pearson")
)
```

Arguments

`kappa1`	Expected agreement under the alternative hypothesis.
`kappa0`	Agreement under the null hypothesis.
`prevalence`	Expected prevalence.
`alpha`	Type I error.
`power`	Desired power.
`response.rate`	Expected response rate.
`dropout`	Expected dropout proportion.
`method`	Character string.

Details

Computes the required sample size for studies evaluating agreement between two binary diagnostic methods.

Value

SampleSizeR object.

`ss_diagnostic_auc` *Sample Size for ROC Area Under the Curve (AUC)*

Description

Calculates the required sample size for studies evaluating the area under the receiver operating characteristic (ROC) curve.

Usage

```
ss_diagnostic_auc(
  auc,
  auc0 = 0.5,
  prevalence,
  precision = NULL,
  alpha = 0.05,
  power = 0.8,
  ratio = 1,
  design = c("precision", "hypothesis"),
  alternative = c("two.sided", "one.sided"),
  method = c("obuchowski", "hanley"),
  response.rate = 1,
  dropout = 0
)
```

Arguments

`auc`	Expected AUC.
`auc0`	Null AUC for hypothesis testing.
`prevalence`	Expected disease prevalence.
`precision`	Desired half-width of the confidence interval. Required only when design="precision".
`alpha`	Type I error.
`power`	Statistical power.
`ratio`	Ratio of non-diseased:diseased subjects.
`design`	Either "precision" or "hypothesis".
`alternative`	One- or two-sided hypothesis.

`method`	Variance estimator.
`response.rate`	Expected response rate.
`dropout`	Expected dropout proportion.

Details

Two study designs are supported:

- Precision-based estimation of AUC
- Hypothesis testing of AUC

Two variance estimators are available:

- Obuchowski (default)
- Hanley & McNeil

Value

Object of class SampleSizeR.

References

Obuchowski NA. Statistics in Medicine. 1994.

Hanley JA, McNeil BJ. Radiology. 1982.

Zhou XH, Obuchowski NA, McClish DK. Statistical Methods in Diagnostic Medicine.

`ss_diagnostic_sensitivity`

Sample Size for Diagnostic Test Sensitivity

Description

Calculates the required sample size to estimate the sensitivity of a diagnostic test with a specified confidence interval precision using the method of Buderer (1996).

Usage

```
ss_diagnostic_sensitivity(
  sensitivity,
  prevalence,
  precision = 0.05,
  conf.level = 0.95,
  finite.population = NULL,
  response.rate = 1,
  dropout = 0
)
```

Arguments

`sensitivity`	Expected sensitivity of the diagnostic test (0 < sensitivity < 1).
`prevalence`	Expected disease prevalence (0 < prevalence < 1).
`precision`	Desired absolute precision (half-width of the confidence interval).
`conf.level`	Confidence level.
`finite.population`	Optional finite population size.
`response.rate`	Expected response rate ($0 < response.rate \leq 1$).
`dropout`	Expected dropout proportion ($0 \leq dropout < 1$).

Details

The Buderer (1996) method estimates the total sample size required to achieve the desired precision for the sensitivity estimate while accounting for the expected prevalence of disease.

The required number of diseased subjects is

$$n_D = \frac{Z^2 Se(1 - Se)}{L^2}$$

The total sample size is

$$n = \frac{n_D}{Prev}$$

Value

An object of class `"SampleSizeR"`.

References

Buderer NM. Statistical Methodology: Incorporating the Prevalence of Disease into the Sample Size Calculation for Sensitivity and Specificity. Academic Emergency Medicine. 1996.

Flahault A, Cadilhac M, Thomas G. Sample size calculation should be performed for design accuracy in diagnostic test studies. Journal of Clinical Epidemiology. 2005.

Examples

```
ss_diagnostic_sensitivity(
    sensitivity = 0.90,
    prevalence = 0.25,
    precision = 0.05
)
```

`ss_diagnostic_specificity` *Sample Size for Diagnostic Test Specificity*

Description

Calculates the required sample size to estimate the specificity of a diagnostic test with a specified confidence interval precision using the method of Buderer (1996).

Usage

```
ss_diagnostic_specificity(
  specificity,
  prevalence,
  precision = 0.05,
  conf.level = 0.95,
  finite.population = NULL,
  response.rate = 1,
  dropout = 0
)
```

Arguments

`specificity`	Expected specificity of the diagnostic test (0 < specificity < 1).
`prevalence`	Expected disease prevalence (0 < prevalence < 1).
`precision`	Desired absolute precision (half-width of the confidence interval).
`conf.level`	Confidence level.
`finite.population`	Optional finite population size.
`response.rate`	Expected response rate ($0 < response.rate \leq 1$).
`dropout`	Expected dropout proportion ($0 \leq dropout < 1$).

Details

The Buderer (1996) method estimates the total sample size required to achieve the desired precision for the specificity estimate while accounting for the expected prevalence of disease.

The required number of non-diseased subjects is

$$n_{ND} = \frac{Z^2 Sp(1 - Sp)}{L^2}$$

The total sample size is

$$n = \frac{n_{ND}}{1 - Prev}$$

Value

An object of class "SampleSizeR".

References

Buderer NM. Statistical Methodology: Incorporating the Prevalence of Disease into the Sample Size Calculation for Sensitivity and Specificity. Academic Emergency Medicine. 1996.

Flahault A, Cadilhac M, Thomas G. Sample size calculation should be performed for design accuracy in diagnostic test studies. Journal of Clinical Epidemiology. 2005.

Examples

```
ss_diagnostic_specificity(
    specificity = 0.95,
    prevalence = 0.30,
    precision = 0.05
)
```

---

ss_equivalence_trial *Sample Size for an Equivalence Trial*

Description

Calculates the required sample size for a two-arm parallel equivalence clinical trial using the Two One-Sided Tests (TOST) procedure.

Usage

```
ss_equivalence_trial(
  outcome = c("continuous", "binary"),
  alpha = 0.05,
  power = 0.8,
  ratio = 1,
  dropout = 0,
  delta,
  mean1 = NULL,
  mean2 = NULL,
  sd = NULL,
  p1 = NULL,
  p2 = NULL
)
```

Arguments

outcome	Either "continuous" or "binary".
alpha	Type I error (typically 0.05).
power	Statistical power.
ratio	Allocation ratio (Control : Treatment).
dropout	Expected dropout proportion.
delta	Positive equivalence margin.
mean1	Treatment mean.
mean2	Control mean.
sd	Common standard deviation.
p1	Treatment event probability.
p2	Control event probability.

Details

Supported endpoints:

- Continuous
- Binary (Risk Difference)

Supports equal or unequal allocation ratios.

Value

Object of class "SampleSizeR".

References

Chow SC, Shao J, Wang H. Sample Size Calculations in Clinical Research.

Piaggio G et al. Reporting of Noninferiority and Equivalence Randomized Trials.

ICH E9 Statistical Principles for Clinical Trials.

Examples

```
ss_equivalence_trial(
    outcome = "continuous",
    mean1 = 100,
    mean2 = 102,
    sd = 12,
    delta = 5
)

ss_equivalence_trial(
    outcome = "binary",
    p1 = 0.80,
    p2 = 0.78,
    delta = 0.10
```

```
)
```

`ss_noninferiority_trial` *Sample Size for a Non-Inferiority Trial*

Description

Calculates the required sample size for a two-arm parallel non-inferiority clinical trial.

Usage

```
ss_noninferiority_trial(
  outcome = c("continuous", "binary"),
  alpha = 0.025,
  power = 0.8,
  alternative = c("one.sided", "two.sided"),
  ratio = 1,
  dropout = 0,
  delta,
  mean1 = NULL,
  mean2 = NULL,
  sd = NULL,
  p1 = NULL,
  p2 = NULL
)
```

Arguments

`outcome`	Either "continuous" or "binary".
`alpha`	Type I error.
`power`	Statistical power.
`alternative`	One-sided or two-sided test.
`ratio`	Allocation ratio (Control : Treatment).
`dropout`	Dropout proportion.
`delta`	Non-inferiority margin (positive).
`mean1`	Treatment mean.
`mean2`	Control mean.
`sd`	Common standard deviation.
`p1`	Treatment event probability.
`p2`	Control event probability.

Details

Supported endpoints:

- Continuous
- Binary

Supports equal or unequal allocation ratios.

Value

Object of class SampleSizeR.

References

Chow SC, Shao J, Wang H. Sample Size Calculations in Clinical Research.

ICH E9.

Piaggio G et al. Reporting of Noninferiority and Equivalence Randomized Trials.

`ss_prevalence` *Sample Size for a Prevalence Study*

Description

Calculates the minimum required sample size for estimating disease prevalence with a specified confidence level and desired precision.

Usage

```
ss_prevalence(
  prevalence,
  precision = NULL,
  relative.precision = NULL,
  conf.level = 0.95,
  finite.population = NULL,
  design.effect = 1,
  response.rate = 1,
  dropout = 0
)
```

Arguments

`prevalence`	Expected prevalence (0–1).
`precision`	Absolute precision (0–1). Ignored if `relative.precision` is supplied.
`relative.precision`	Relative precision expressed as a proportion of prevalence (e.g. 0.20 = ±20% of prevalence).

`conf.level`	Confidence level. Default is 0.95.
`finite.population`	Population size for finite population correction. Default is NULL.
`design.effect`	Design effect (>=1). Default is 1.
`response.rate`	Expected response rate (0–1). Default is 1.
`dropout`	Expected dropout proportion (0–1). Default is 0.

Details

The function implements Cochran's sample size formula and optionally adjusts for:

- finite population correction (FPC)
- design effect
- anticipated non-response

Relative precision can also be specified.

Cochran's formula

$$n = \frac{Z^2 P(1-P)}{d^2}$$

where

- P = expected prevalence
- d = desired precision
- Z = Normal quantile corresponding to confidence level

If a finite population size is supplied, finite population correction is applied.

The resulting sample size is subsequently adjusted for

- design effect
- anticipated non-response
- dropout

Value

An object of class `SampleSizeR`.

References

Cochran WG (1977). Sampling Techniques. Third Edition. John Wiley & Sons.

Lwanga SK, Lemeshow S (1991). Sample Size Determination in Health Studies. WHO.

Naing L, Winn T, Rusli BN (2006). Practical issues in calculating the sample size for prevalence studies. Archives of Orofacial Sciences.

Examples

```
ss_prevalence(
  prevalence = 0.20,
  precision = 0.05
)

ss_prevalence(
  prevalence = 0.10,
  relative.precision = 0.20
)

ss_prevalence(
  prevalence = 0.15,
  precision = 0.04,
  finite.population = 2500
)
```

---

ss_prevalence_cluster *Sample Size for Cluster Prevalence Studies*

Description

Calculates the required sample size for estimating prevalence using a cluster sampling design.

Usage

```
ss_prevalence_cluster(
  prevalence,
  precision = NULL,
  relative.precision = NULL,
  cluster.size,
  icc,
  conf.level = 0.95,
  finite.population = NULL,
  response.rate = 1,
  dropout = 0
)
```

Arguments

prevalence	Expected prevalence (0–1).
precision	Absolute precision.
relative.precision	Relative precision.
cluster.size	Average number of subjects per cluster.
icc	Intra-cluster correlation coefficient.

`conf.level`	Confidence level.
`finite.population`	Population size.
`response.rate`	Expected response proportion.
`dropout`	Expected dropout proportion.

Details

The function first computes the simple random sample size using Cochran's formula and then inflates the sample size using the cluster design effect:

$$DEFF = 1 + (m - 1)\rho$$

where

- m = average cluster size
- ρ = intra-cluster correlation coefficient (ICC)

The function optionally adjusts for

- finite population
- non-response
- dropout

Value

Object of class `SampleSizeR`

References

Cochran WG (1977). Sampling Techniques.

Donner A, Klar N (2000). Design and Analysis of Cluster Randomization Trials.

Hayes RJ, Bennett S (1999). Simple sample size calculation for cluster-randomized trials.

Examples

```
ss_prevalence_cluster(
prevalence=0.20,
precision=0.05,
cluster.size=20,
icc=0.05
)
```

`ss_superiority_trial` *Sample Size for a Superiority Trial*

Description

Calculates the required sample size for a two-arm superiority clinical trial with either continuous or binary endpoints.

Usage

```
ss_superiority_trial(
  outcome = c("continuous", "binary"),
  alpha = 0.05,
  power = 0.8,
  alternative = c("two.sided", "one.sided"),
  ratio = 1,
  dropout = 0,
  delta,
  mean1 = NULL,
  mean2 = NULL,
  sd = NULL,
  p1 = NULL,
  p2 = NULL
)
```

Arguments

`outcome`	Character string. Either `"continuous"` or `"binary"`.
`alpha`	Type I error.
`power`	Statistical power.
`alternative`	`"one.sided"` or `"two.sided"`.
`ratio`	Allocation ratio (Control : Treatment).
`dropout`	Expected dropout proportion.
`delta`	Superiority margin.
`mean1`	Treatment mean.
`mean2`	Control mean.
`sd`	Common standard deviation.
`p1`	Treatment event probability.
`p2`	Control event probability.

Details

Supports

- Continuous outcomes
- Binary outcomes
- One-sided superiority tests
- Two-sided superiority tests
- Unequal allocation ratios

Value

Object of class SampleSizeR.

References

Chow SC, Shao J, Wang H. Sample Size Calculations in Clinical Research.

ICH E9 Statistical Principles for Clinical Trials.

Julious SA. Sample Sizes for Clinical Trials.

Examples

```
ss_superiority_trial(
    outcome="continuous",
    mean1=16,
    mean2=12,
    sd=6,
    delta=2
)

ss_superiority_trial(
    outcome="binary",
    p1=0.70,
    p2=0.55,
    delta=0.05
)
```

---

summary.SampleSizeR *Summary of Sample Size Result*

Description

Summary of Sample Size Result

Usage

```
## S3 method for class 'SampleSizeR'
summary(object, ...)
```

Arguments

`object`	A SampleSizeR object.
`...`	Additional arguments.

Value

Object of class summary.SampleSizeR.

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