

Package: ssutil (via r-universe)

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Title Sample Size Calculation Tools

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Description Functions for sample size estimation and simulation in clinical trials. Includes methods for selecting the best group using the Indifference-zone approach, as well as designs for non-inferiority, equivalence, and negative binomial models. For the sample size calculation for non-inferiority of vaccines, the approach is based on Fleming, Powers, and Huang (2021) <[doi:10.1177/1740774520988244](https://doi.org/10.1177/1740774520988244)>. The Indifference-zone approach is based on Sobel and Huyett (1957) <[doi:10.1002/j.1538-7305.1957.tb02411.x](https://doi.org/10.1002/j.1538-7305.1957.tb02411.x)> and Bechhofer, Santner, and Goldsman (1995, ISBN:978-0-471-57427-9).

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empirical_power_result

Create an Empirical Power Result object

Description

Constructs an S3 object of class `empirical_power_result`, storing the estimated power, its confidence interval, and the number of simulations used to compute it.

Usage

```
empirical_power_result(x, n, conf.level = 0.95)
```

Arguments

<code>x</code>	Number of successes
<code>n</code>	Number of trials.
<code>conf.level</code>	Confidence level for the returned confidence interval power.

Details

It is a wrap to [binom.test](#)

Value

An object of class `empirical_power_result`, a list with components:

- `power`: Estimated power.
- `conf.low`: Lower bound of confidence interval.
- `conf.high`: Upper bound of confidence interval.
- `conf.level`: Confidence level for the returned confidence interval.
- `nsim`: Number of simulations.

Examples

```
result <- empirical_power_result(  
  x = 10,  
  n = 100,  
  conf.level = 0.95  
)  
print(result)
```

`format.power_single_rate`

Format method for power_single_rate class

Description

Format method for `power_single_rate` class

Usage

```
## S3 method for class 'power_single_rate'  
format(x, digits = 3, ...)
```

Arguments

<code>x</code>	an R object of class <code>power_single_rate</code>
<code>digits</code>	a positive integer indicating how many significant digits are to be used for numeric <code>x</code> .
<code>...</code>	further arguments passed to or from other methods

Value

A character string with a human-readable summary of the detection power or a markdown-style table, depending on the number of rows.

```
is.empirical_power_result
```

Check if an object is a sim_power_result

Description

Check if an object is a sim_power_result

Usage

```
is.empirical_power_result(x)
```

Arguments

x Any R object.

Value

Logical. TRUE if x inherits from "sim_power_result".

```
multp
```

Calculate the Multivariate Normal Probability

Description

Computes the multivariate normal probabilities with arbitrary correlation matrices It is the inverse of the multz function

Usage

```
multp(q, k, rho, seed = NULL)
```

Arguments

q Numeric. Quantile of the distribution.

k Integer. Number of variables in the multivariate normal distribution. Must be ≥ 1 .

rho Numeric. Common correlation coefficient between variables (typically between 0 and 1).

seed Optional. An object specifying if and how the random number generator should be initialized. Passed to [pmvnorm](#).

Value

Numeric. The multivariate probability

Examples

```
q <- 1.3
k <- 3
rho <- 0.5
multp(q, k, rho)
```

multz	<i>Calculate the Upper Equicoordinate Point of a Multivariate Normal Distribution</i>
-------	---

Description

Computes the upper equicoordinate quantile for a multivariate standard normal distribution with unit variances and a common correlation coefficient ρ . That is, it returns the value z such that the joint probability $P(X_1 \leq z, \dots, X_n \leq z) = 1 - \alpha$.

Usage

```
multz(alpha, k, rho, seed = NULL)
```

Arguments

alpha	Numeric. Significance level (e.g., 0.05 for a 95% confidence level).
k	Integer. Number of variables in the multivariate normal distribution. Must be ≥ 1 .
rho	Numeric. Common correlation coefficient between variables (typically between 0 and 1).
seed	Optional. An object specifying if and how the random number generator should be initialized. Passed to qmvnorm .

Value

Numeric. The upper equicoordinate point z such that the joint probability of all variables being less than or equal to z is $1 - \alpha$.

Examples

```
alpha <- 0.1 # Significance level (10%)
k <- 3      # Number of variables
rho <- 0.5  # Common correlation coefficient
multz(alpha, k, rho)
```

power_best_binomial *Power to Correctly Select the Best Group in a Binomial Test*

Description

Computes the exact probability of correctly identifying the best group when the outcome follows a binomial distribution. It assumes that p_1 is the probability of success in the best group, and that the success probability in all other groups is lower by a fixed difference dif .

Usage

```
power_best_binomial(p1, dif, ngroups, npergroup)
```

Arguments

<code>p1</code>	Numeric. Probability of success in the best group (must be in $[0, 1]$).
<code>dif</code>	Numeric. Difference in success probability between the best group and the next best (must be > 0).
<code>ngroups</code>	Integer. Number of groups (must be greater than 1).
<code>npergroup</code>	Integer. Number of subjects per group (must be positive).

Details

The formula is based on the exact method described by Sobel and Huyett (1957).

Value

A numeric value representing the probability of correctly identifying the best group.

References

Sobel, M., & Huyett, M. J. (1957). Selecting the Best One of Several Binomial Populations. *Bell System Technical Journal*, 36(2), 537–576. doi:10.1002/j.15387305.1957.tb02411.x

Examples

```
power_best_binomial(p1 = 0.8, dif = 0.2, ngroups = 4, npergroup = 50)
```

power_best_normal	<i>Power calculation for the Indifferent-zone approach for normal outcomes</i>
-------------------	--

Description

Estimate the probability of correctly select the best group among `ngroups` groups if the difference between the best group and the next best is at least `dif`(the Indifferent-Zone), and the standard deviation is `sd`

Usage

```
power_best_normal(dif, sd, ngroups, npergroup, seed = NULL)
```

Arguments

<code>dif</code>	Numeric. Indifferent-zone. Minimum difference that is considered meaningful.
<code>sd</code>	Numeric. Common standard deviation of the response variable.
<code>ngroups</code>	Integer. Number of groups (treatments) being compared.
<code>npergroup</code>	Integer. Number in each group.
<code>seed</code>	Optional. Integer seed to use in the internal call to <code>multp()</code> .

Value

Integer. Sample size required per group to achieve the specified power.

Note

The function uses the quantile function `multp()`, which computes critical values for the selection procedure. This implementation assumes equal variances and independent samples.

Examples

```
power_best_normal(dif = 0.5, sd = 1, ngroups = 3, npergroup = 11)
```

`power_single_rate` *Detectable Event Rate with Specified Power and Sample Size*

Description

Estimates the minimum true proportion of events needed to detect at least one event, given a sample size and desired statistical power.

Usage

```
power_single_rate(subjects, power)
```

Arguments

`subjects` Integer or vector of integers. Sample size(s).
`power` Numeric or vector of numerics. Desired power(s), between 0 and 1.

Value

A matrix of class `power_single_rate` with columns:

n Sample size

power Requested power

proportion Minimum detectable event rate to observe at least one event

Examples

```
power_single_rate(30, 0.9)
power_single_rate(c(30, 50, 100), 0.9)
```

`print.empirical_power_result`

Print method for empirical_power_result

Description

Nicely formats the output of an object of class `empirical_power_result`, showing the power estimate, confidence interval, and number of simulations.

Usage

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

Arguments

- x An object of class "empirical_power_result".
- ... Further arguments passed to or from other methods (ignored).

Value

Invisibly returns the object passed in.

`print.power_single_rate`
Print method for class power_single_rate

Description

Print method for class power_single_rate

Usage

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

Arguments

- x an object of class power_single_rate
- ... further arguments passed to or from other methods

Value

Invisibly returns the object passed in.

`prophr` *Calculate Event Probability in the Experimental Group Given a Hazard Ratio*

Description

Computes the event probability in the experimental group based on the event probability in the control group and a specified hazard ratio, assuming proportional hazards.

Usage

```
prophr(p0, hr)
```

Arguments

<code>p0</code>	Numeric scalar. Probability of an event in the control group (between 0 and 1).
<code>hr</code>	Numeric scalar. Hazard ratio (must be > 0).

Details

This is useful for sample size calculations, for example in PASS (TM), which does not automatically adjust the event rate for the experimental group.

Value

Numeric. The probability of an event in the experimental group.

Examples

```
prophr(0.05, 0.6)
```

```
sim_power_best_bin_rank
```

Simulate Power to Rank the Best Group Using Binomial Outcomes

Description

Estimates the empirical power to rank the most promising group as the best, based on binomial outcomes, via simulation.

Usage

```
sim_power_best_bin_rank(  
  noutcomes,  
  p1,  
  dif,  
  weights,  
  ngroups,  
  npergroup,  
  nsim,  
  conf.level = 0.95  
)
```

Arguments

<code>noutcomes</code>	Integer. Number of outcomes to evaluate.
<code>p1</code>	Numeric. Event probability in the best group (scalar or vector of length <code>noutcomes</code>).
<code>dif</code>	Numeric. Difference between the best group and the rest (scalar or vector of length <code>noutcomes</code>).

weights	Numeric vector. Weights for each outcome. If scalar, applied equally.
ngroups	Integer. Number of groups.
npergroup	Integer or vector. Sample size per group.
nsim	Integer. Number of simulations.
conf.level	Numeric. Confidence level for the empirical power estimate#'

Details

Each outcome is assumed to follow an independent binomial distribution. The best group is defined as having a probability at least `dif` higher than the other groups. The function sums weighted ranks across multiple outcomes to determine the top group.

If multiple outcomes are defined, weights can be applied to prioritize some outcomes over others. Weights are automatically scaled to sum 1. The group with the lowest total rank is considered the best.

Value

An S3 object of class `empirical_power_result`, which contains the estimated empirical power and its confidence interval. The object can be printed, formatted, or further processed using associated S3 methods. See also [empirical_power_result](#).

See Also

[empirical_power_result](#)

Examples

```
sim_power_best_bin_rank(
  noutcomes = 2,
  p1 = 0.80,
  dif = 0.15,
  weights = 1,
  ngroups = 3,
  npergroup = 30,
  nsim = 1000,
  conf.level = 0.95)
```

sim_power_best_binomial

Simulate Power to Select the Best Group Using Binomial Outcomes

Description

Estimates the empirical power to correctly identify the best group as having the highest outcome, under a binomial distribution. Assumes that the most promising group has a higher success probability than the others by at least `dif`, and that outcomes are independent.

Usage

```
sim_power_best_binomial(  
  noutcomes,  
  p1,  
  dif,  
  ngroups,  
  npergroup,  
  nsim,  
  conf.level = 0.95  
)
```

Arguments

noutcomes	Integer. Number of outcomes to evaluate.
p1	Numeric. Probability in the most promising group (scalar or vector).
dif	Numeric. Difference between the best group and the rest.
ngroups	Integer. Number of groups.
npergroup	Integer or vector. Number of subjects per group.
nsim	Integer. Number of simulations.
conf.level	Numeric. Confidence level for the empirical power estimate

Details

Multiple outcomes can be evaluated simultaneously. The power is estimated as the proportion of simulations where the most promising group is selected best in all outcomes.

Value

An S3 object of class `empirical_power_result`, which contains the estimated empirical power and its confidence interval. The object can be printed, formatted, or further processed using associated S3 methods. See also [empirical_power_result](#).

See Also

[empirical_power_result](#)

Examples

```
sim_power_best_binomial(  
  noutcomes = 1,  
  p1 = 0.7,  
  dif = 0.2,  
  ngroups = 3,  
  npergroup = 30,  
  nsim = 1000  
)
```

`sim_power_best_norm_rank`*Simulate Power to Select Best Group by Ranks (Normal Outcomes)*

Description

Estimates the empirical power to identify the most promising group as best, using weighted ranks across outcomes, assuming normally distributed outcomes.

Usage

```
sim_power_best_norm_rank(  
  noutcomes,  
  sd,  
  dif,  
  weights,  
  ngroups,  
  npergroup,  
  nsim,  
  conf.level = 0.95  
)
```

Arguments

<code>noutcomes</code>	Integer. Number of outcomes to evaluate.
<code>sd</code>	Numeric vector. Standard deviations for each outcome.
<code>dif</code>	Numeric vector. Difference in means between the best and other groups.
<code>weights</code>	Numeric vector. Weights per outcome.
<code>ngroups</code>	Integer. Number of groups.
<code>npergroup</code>	Integer or vector. Number of subjects per group.
<code>nsim</code>	Integer. Number of simulations.
<code>conf.level</code>	Numeric. Confidence level for the empirical power estimate

Details

Each outcome is independent and normally distributed. The most promising group is assumed to have a mean at least `dif` higher than the others. Ranks are weighted and summed per group across outcomes.

If `weights` is specified, it is internally scaled to sum to 1. The most promising group is always considered to be the first group.

Value

An S3 object of class `empirical_power_result`, which contains the estimated empirical power and its confidence interval. The object can be printed, formatted, or further processed using associated S3 methods. See also [empirical_power_result](#).

See Also

[empirical_power_result](#)

Examples

```
sim_power_best_norm_rank(
  noutcomes = 3,
  sd = c(1, 0.8, 1.5),
  dif = c(0.2, 0.15, 0.3),
  weights = c(0.5, 0.3, 0.2),
  ngroups = 3,
  npergroup = c(30, 25, 25),
  nsim = 1000
)
```

sim_power_best_normal *Simulate Power to Select Best Group (Normal Outcomes)*

Description

Estimates the empirical power to identify the most promising group as the best, when outcomes are normally distributed and independent.

Usage

```
sim_power_best_normal(
  noutcomes,
  sd,
  dif,
  ngroups,
  npergroup,
  nsim,
  conf.level = 0.95
)
```

Arguments

noutcomes	Integer. Number of outcomes to evaluate.
sd	Numeric vector. Standard deviations for each outcome. Can be a single value.
dif	Numeric vector. Difference in means between the best and the other groups.
ngroups	Number of groups to compare.
npergroup	Number of subjects per group. Can be scalar or vector of length ngroups.
nsim	Integer. Number of simulations to perform.
conf.level	Numeric. Confidence level for the empirical power estimate

Details

The best group (group 1) is assumed to have mean 0, and the rest of the groups have mean $-dif$.

Multiple outcomes can be evaluated simultaneously. The power is estimated as the proportion of simulations where the most promising group is the best in all outcomes.

The number of subjects per group can be the same or specified per group. In either case, the first group is assumed to be the most promising.

Value

An S3 object of class `empirical_power_result`, which contains the estimated empirical power and its confidence interval. The object can be printed, formatted, or further processed using associated S3 methods. See also [empirical_power_result](#).

See Also

[empirical_power_result](#)

Examples

```
sim_power_best_normal(  
  noutcomes = 2,  
  sd = c(1, 1.2),  
  dif = c(0.2, 0.25),  
  ngroups = 3,  
  npergroup = c(30, 25, 25),  
  nsim = 1000  
)
```

sim_power_equivalence_normal

Empirical Power for Equivalence (Normal Outcomes)

Description

Estimates the empirical power to detect equivalence among multiple groups assuming no true difference in normally distributed outcomes. Pairwise two-sample t-tests are used, and equivalence is declared if all confidence intervals for differences between group means lie entirely within the interval defined by `llimit` and `ulimit`.

Usage

```
sim_power_equivalence_normal(  
  ngroups,  
  npergroup,  
  sd,  
  llimit,  
  ulimit,
```

```

    nsim,
    t_level = 0.95,
    conf.level = 0.95
  )

```

Arguments

<code>ngroups</code>	Integer. Number of groups to compare
<code>npergroup</code>	Integer. Number of observations per group.
<code>sd</code>	Numeric. Standard deviation of the outcome distribution (common across groups).
<code>llimit</code>	Numeric. Lower equivalence limit.
<code>ulimit</code>	Numeric. Upper equivalence limit.
<code>nsim</code>	Integer. Number of simulations to perform.
<code>t_level</code>	Numeric. Confidence level used for the t-tests (e.g., 0.95 for 95% CI).
<code>conf.level</code>	Numeric. Confidence level for the empirical power estimate

Details

This function simulates data under the null hypothesis of no difference between groups and calculates the proportion of simulations in which all pairwise comparisons fall within the specified equivalence limits.

Value

An S3 object of class `empirical_power_result`, which contains the estimated empirical power and its confidence interval. The object can be printed, formatted, or further processed using associated S3 methods. See also [empirical_power_result](#).

See Also

[empirical_power_result](#)

Examples

```

#Equivalence testing for three groups with log-scale outcome
sim_power_equivalence_normal(
  ngroups = 3,
  npergroup = 172,
  sd = 0.403,
  llimit = log10(2/3),
  ulimit = log10(3/2),
  nsim = 1000,
  t_level = 0.95
)

```

`sim_power_nbinom`*Empirical Power for Negative Binomial Comparison*

Description

Estimates empirical power to detect a relative risk either above or below a specified boundary, depending on the direction of the alternative hypothesis. Simulates count data with over dispersion, fits a model with `glm.nb`, and evaluates the power to reject the null hypothesis using a negative binomial model.

Usage

```
sim_power_nbinom(  
  n1,  
  n2,  
  ir1,  
  tm,  
  rr,  
  boundary,  
  dispersion,  
  alpha,  
  nsim,  
  conf.level = 0.95  
)
```

Arguments

<code>n1</code>	Integer. Number of participants in group 1.
<code>n2</code>	Integer. Number of participants in group 2.
<code>ir1</code>	Numeric. Incidence rate in group 1.
<code>tm</code>	Numeric. Average exposure time per subject (assumed equal across subjects).
<code>rr</code>	Numeric. True relative risk between groups (group 2 rate = $rr \times$ group 1 rate).
<code>boundary</code>	Numeric. Relative risk boundary under the null hypothesis.
<code>dispersion</code>	Numeric. Dispersion parameter (ϕ) for the negative binomial distribution.
<code>alpha</code>	Numeric. Type I error rate (two-sided).
<code>nsim</code>	Integer. Number of simulation iterations.
<code>conf.level</code>	Numeric. Confidence level for the empirical power estimate

Value

An S3 object of class `empirical_power_result`, which contains the estimated empirical power and its confidence interval. The object can be printed, formatted, or further processed using associated S3 methods. See also [empirical_power_result](#).

Note

Uses the alternative parameterization of the negative binomial: μ is the mean, and $\text{size} = 1/\text{dispersion}$. In `glm.nb`, dispersion is estimated as θ . The 'boundary' parameter defines the relative risk under the null hypothesis. When $rr < 1$, rejection occurs if the upper limit of the confidence interval is below the boundary. When $rr > 1$, rejection occurs if the lower limit is above the boundary.

The alpha parameter is two-sided as it is used to estimate two-sided confidence intervals

Author(s)

Chris Gast

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See Also

[empirical_power_result](#)

Examples

```
sim_power_nbinom(  
  n1 = 150, n2 = 150,  
  ir1 = 0.55, tm = 1.7,  
  rr = 0.6, boundary = 1,  
  dispersion = 2,  
  alpha = 0.05,  
  nsim = 1000  
)
```

sim_power_ni_normal *Empirical Power for Non-Inferiority (Normal Outcomes)*

Description

Estimates empirical power to declare non-inferiority between two groups across multiple outcomes using t-tests. Simulates normally distributed data under the null (no difference) and applies non-inferiority rules based on user-defined required and optional tests.

Usage

```
sim_power_ni_normal(  
  nsim,  
  npergroup,  
  ntest,  
  ni_limit,  
  test_req,  
  test_opt,  
  sd,
```

```

    corr = 0,
    t_level = 0.95,
    conf.level = 0.95
  )

```

Arguments

nsim	Integer. Number of simulations to perform.
npergroup	Integer. Number of observations per group.
ntest	Integer. Number of tests (outcomes) to compare.
ni_limit	Numeric. Limit to declare non-inferiority. Can be a scalar or vector of length ntest.
test_req	Integer. Number of required tests that must show non-inferiority (first test_req tests).
test_opt	Integer. Number of optional tests that must also show non-inferiority from the remaining tests.
sd	Numeric. Standard deviation(s) of the outcomes. Scalar or vector of length ntest.
corr	Numeric. Correlation between the tests. Scalar (common correlation), or vector of length $ntest*(ntest-1)/2$.
t_level	Numeric. Confidence level used for the t-tests (e.g., 0.95 for 95% CI). scalar or vector of length ntest.
conf.level	Numeric. Confidence level for the empirical power estimate

Details

A test is considered non-inferior if the lower bound of its confidence interval is greater than the specified non-inferiority limit. Overall non-inferiority is declared if all test_req and at least test_opt of the remaining tests are non-inferior.

Value

An S3 object of class `empirical_power_result`, which contains the estimated empirical power and its confidence interval. The object can be printed, formatted, or further processed using associated S3 methods. See also [empirical_power_result](#).

Note

If only one test is used, correlation is ignored.

Use correlation 0 for independent outcomes

When using a correlation vector, it must match the number of test pairs: $ntest*(ntest-1)/2$, in this order: (1,2), (1,3), ..., (1,ntest), (2,3), ..., (ntest-1,ntest).

The covariance matrix is derived from the correlation matrix and the standard deviations.

For example: with $ntest = 3$ and $corr = c(0.2, 0.3, 0.4)$, the resulting correlation matrix is:

	[,1]	[,2]	[,3]
[1,]	1	0.2	0.3
[2,]	0.2	1	0.4
[3,]	0.3	0.4	1

See Also

[empirical_power_result](#)

Examples

```
sim_power_ni_normal(
  nsim = 1000,
  npergroup = 250,
  ntest = 7,
  ni_limit = log10(2/3),
  test_req = 2,
  test_opt = 3,
  sd = 0.4,
  corr = 0,
  t_level = 0.05
)
```

ss_best_binomial

Sample Size to Select the Best Group in a Binomial Test

Description

Computes the minimum sample size per group required to achieve a target probability of correctly selecting the best group in a binomial test. The best group is assumed to have success probability p_1 , and the other groups have $p_1 - \text{dif}$.

Usage

```
ss_best_binomial(power, p1, dif, ngroups, max_n = 1000)
```

Arguments

power	Numeric. Desired probability of correctly selecting the best group (in [0, 1]).
p1	Numeric. Probability of success in the best group (in [0, 1]).
dif	Numeric. Difference in success probability with the next best group (> 0).
ngroups	Integer. Number of groups (must be > 1).
max_n	Integer. Maximum sample size to evaluate (default is 1000).

Details

The function searches for the smallest npergroup such that the power from `power_best_binomial` is at least the target power.

Value

An integer representing the minimum sample size per group required to reach the specified power.

Examples

```
ss_best_binomial(power = 0.9, p1 = 0.8, dif = 0.2, ngroups = 4)
```

ss_best_normal	<i>Sample Size for Selecting the Best Treatment in a Normal Response (Indifference-Zone)</i>
----------------	--

Description

Calculates the minimum common sample size per group needed to achieve a specified probability (power) of correctly selecting the best group using the indifference-zone approach. This method assumes normally distributed responses with a known and common standard deviation.

Usage

```
ss_best_normal(power, dif, sd, ngroups, seed = NULL)
```

Arguments

power	Numeric. Desired probability of correctly selecting the best group.
dif	Numeric. Indifferent-zone. Minimum difference that is considered meaningful.
sd	Numeric. Common standard deviation of the response variable.
ngroups	Integer. Number of groups (treatments) being compared.
seed	Optional. Integer seed to use in the internal call to <code>multz()</code> .

Details

The indifference-zone approach guarantees that the probability of correct selection is at least power, assuming the best group's mean exceeds the others by at least dif. The calculation is based on Bechhofer's Procedure Nb.

Value

Integer. Sample size required per group to achieve the specified power.

Note

The function uses the quantile function `multz()`, which computes critical values for the selection procedure. This implementation assumes equal variances and independent samples.

References

Bechhofer, R.E., Santner, T.J., & Goldsman, D.M. (1995). *Design and Analysis of Experiments for Statistical Selection, Screening, and Multiple Comparisons*. Wiley Series in Probability and Statistics. ISBN: 0-471-57427-9.

Examples

```
ss_best_normal( power = 0.8, dif = 0.5, sd = 1, ngroups = 3)
```

 ss_ni_ve

Sample Size and Non-Inferiority Margin for Vaccine Efficacy Trials

Description

Computes the non-inferiority margin, number of events, and maximum hazard ratio (HR) to declare non-inferiority in vaccine efficacy (VE) trials, based on the approach described by Fleming et al. (2021).

Usage

```
ss_ni_ve(ve_lci, alpha = 0.025, power = 0.9, use70 = FALSE, preserve = 0.5)
```

Arguments

ve_lci	Numeric. Lower bound of the current vaccine's efficacy (e.g., 0.95 for 95% VE).
alpha	Numeric. Type I error rate (default = 0.025).
power	Numeric. Desired power for the test (default = 0.90).
use70	Logical. If TRUE, assumes at least 30% VE for the new vaccine (the 90–70 rule); otherwise, preserves a fixed fraction of the reference VE.
preserve	Numeric. Proportion of the current vaccine's efficacy to preserve under use70 = FALSE (default = 0.5).

Details

The method applies either the 95–95 rule or 90–70 rule, depending on whether a minimum VE of 30% is assumed (use70 = TRUE) or 50% of the current VE is preserved.

This implementation approximates Table 1 of the paper using exact binomial confidence intervals via `binom.test` and the `nBinomial1Sample` function from **gsDesign**.

Value

A named list with:

- Upper limit of the HR used to estimate the sample size: Hazard ratio corresponding to `ve_lci`.
- Non-inferior margin in HR scale: Non-inferiority margin expressed as a hazard ratio.
- Alpha: The type I error used.
- Power: The power used.
- Total number of events: Total number of events required in the trial.
- Max HR to declare NI: Maximum observed hazard ratio that satisfies the non-inferiority criterion.
- Max number of events in the experimental group: Maximum number of events in the experimental group still compatible with non-inferiority.
- Non-inferior criteria: Description of the applied non-inferiority rule ("At least 30% VE" or "or preserved effect").

References

Fleming, T.R., Powers, J.H., & Huang, Y. (2021). The use of active controls and non-inferiority studies in evaluating COVID-19 vaccines. *Clinical Trials*, 18(3), 335–342. doi:10.1177/1740774520988244

Examples

```
ss_ni_ve(ve_lci = 0.95)
```

```
tidy.empirical_power_result
```

Tidy Method for empirical_power_result

Description

Creates a one-row tibble with the power estimate and confidence interval.

Usage

```
## S3 method for class 'empirical_power_result'
tidy(x, ...)
```

Arguments

```
x          A empirical_power_result object.
...        Ignored.
```

Value

A tibble with columns: `power`, `conf.low`, `conf.high`, `conf.level`, `nsim`.

`wcs_power_best_binomial`*Worst-Case Scenario Power for the Best Binomial Group*

Description

Searches for the probability in the best-performing group that yields the lowest statistical power, given an indifference zone specification, a number of groups, and a number of subjects per group.

Usage

```
wcs_power_best_binomial(dif, ngroups, npergroup)
```

Arguments

<code>dif</code>	Numeric. Indifference zone specification (difference threshold).
<code>ngroups</code>	Integer. Number of groups to compare.
<code>npergroup</code>	Integer. Number of subjects per group.

Details

Defines an internal function `fx` that wraps `power_best_binomial` with the supplied parameters, then uses `optimize` over the interval `[0,1]` to find the probability `p1` that minimizes the resulting power.

Value

A named list with components:

p1 Numeric. Probability in the best group that yields the minimum power.

minimum_power Numeric. The minimum power achieved at `p1`.

See Also

[power_best_binomial](#), [optimize](#)

Examples

```
wcs_power_best_binomial(dif = 0.1, ngroups = 3, npergroup = 50)
```

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