

Package ‘powerHE’

November 15, 2024

Type Package
Title The R 'powerHE' Package
Version 0.1.0
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Description Calculate sample size or power for hierarchical endpoints.
The package can handle any type of outcomes (binary, continuous, count, ordinal, time-to-event), and allows users to find power calculations for win ratios, win odds, net benefits, and DOORs. Given a desired power, the package can calculate the sample size needed.
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Encoding UTF-8
LazyData true
RoxygenNote 7.3.2

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format	<i>Format HE Results</i>
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Description
This formats the results outputted from the HE function

Usage
format(result)

Arguments
result A list

Examples

```
# Example TTE endpoint with formatting

endpoints_input <- list(
  list(type = "TTE",
        hr = 0.8,
        er.b = 0.25,
        s = 12,
        tte.winning.direction = "GT")
)
results <- HE(endpoints_input,
              sample.size = 100,
              alpha = 0.05,
              rratio = 0.5,
              output = "ALL")
format(results)
```

HE

Hierarchical Endpoints

Description

This creates the probability: win, lose, tie, WR, NB, WO, DOOR and creates sample size or power using results.

Usage

```
HE(
  endpoints_input,
  sample.size = NA,
  power = NA,
  alpha = 0.05,
  rratio = 0.5,
  output = "ALL"
)
```

Arguments

`endpoints_input`

A list with each endpoint being a nested list

- Time to Event "TTE":
 - `tte.winning.direction`: winning direction ("GT" or "LT")
 - `er.a` OR `hr`: probability of event in group A OR hazard ratio (group A relative to group B)
 - `er.b`: probability of event in group B
 - `s`: follow-up time
- Continuous "Continuous":
 - `continuous.winning.direction`: winning direction ("GT" or "LT")
 - `mu.a` OR `mean.diff`: mean in group A OR mean difference of group A minus group B

- mu.b: mean in group B
- sd.a: standard deviation in group A
- sd.b: standard deviation in group B
- delta: threshold to win
- Binary (1/0) "Binary":
 - binary.winning.direction: winning direction ("GT" or "LT")
 - pi.a OR prob.diff: Prob(Y=1) in group A OR Prob(Y=1) of group A minus group B
 - pi.b: Prob(Y=1) in group B
- Count Endpoint (such as # of events) "Count":
 - count.winning.direction: winning direction ("GT" or "LT")
 - lam.a OR rr: number of counts/events in group A OR relative rate of group A over group B
 - lam.b: number of counts/events in group B
- Ordinal (1, 2, ..., J) "Ordinal":
 - ordinal.winning.direction: winning direction ("GT" or "LT")
 - pi.ordinal.a: Prob(Y=1), ..., Prob(Y=J) in group A (comma-separated)
 - pi.ordinal.b: Prob(Y=1), ..., Prob(Y=J) in group B (comma-separated)

sample.size An integer (enter either sample.size or power)

power 0 to 1 (enter either sample.size or power)

alpha Two-sided Type 1 Error

rratio Randomization probability for Group A

output Choose from: ALL, WR, WO, NB, DOOR

Examples

```
# Two continuous hierarchical endpoints:
# The marginal distributions for Y1A and Y1B are normal distributions with
# means 15 and 4, respectively, and standard deviations of 60. For Y2A and
# Y2B, the marginal distributions are normal distributions with means 40 and
# 30, respectively, and standard deviations of 24. For both endpoints, the
# threshold to win is chosen to be the same, with both delta1 and delta2
# equal to 5.
# Find the required sample size to achieve a power of 0.85 for win ratios.
```

```
endpoints_input <- list(
  list(type = "Continuous",
    mu.a = 15,
    mu.b = 4,
    sd.a = 60,
    sd.b = 60,
    delta = 5,
    continuous.winning.direction = "GT"),
  list(type = "Continuous",
    mu.a = 40,
    mu.b = 30,
    sd.a = 24,
    sd.b = 24,
    delta = 5,
    continuous.winning.direction = "GT")
)
```

```

HE(endpoints_input,
  power = 0.85,
  alpha = 0.05,
  rratio = 0.5,
  output = "ALL")

# Two binary hierarchical endpoints:
# The marginal probabilities for Y1A and Y1B are binomial distributions with
# a success probability of 0.90 and 0.85, respectively, for one trial. For
# Y2A and Y2B, the marginal probabilities are binomial distributions with
# success probabilities of 0.80 and 0.75, respectively, for one trial.
# Find the achieved power for win ratios with a sample size of 1098.

endpoints_input <- list(
  list(type = "Binary",
    pi.a = 0.9,
    pi.b = 0.85,
    binary.winning.direction = "GT"),
  list(type = "Binary",
    pi.a = 0.8,
    pi.b = 0.75,
    binary.winning.direction = "GT")
)
HE(endpoints_input,
  sample.size = 1098,
  alpha = 0.05,
  rratio = 0.5,
  output = "ALL")

# Binary and continuous hierarchical endpoints:
# The marginal probabilities for Y1A and Y1B are binomial distributions with
# success probabilities of 0.96 and 0.95, respectively, for one trial. For
# Y2A and Y2B, the marginal distributions are normal distributions with means
# 36 and 31, respectively, and standard deviations of 24.
# Find the required sample size to achieve a power of 0.85 for win ratios.

endpoints_input <- list(
  list(type = "Binary",
    pi.a = 0.96,
    pi.b = 0.95,
    binary.winning.direction = "GT"),
  list(type = "Continuous",
    mu.a = 36,
    mu.b = 31,
    sd.a = 24,
    sd.b = 24,
    delta = 5,
    continuous.winning.direction = "GT")
)
HE(endpoints_input,
  power = 0.85,
  alpha = 0.05,
  rratio = 0.5,
  output = "ALL")

# Time to death and number of hospitalizations as hierarchical endpoints:
# The marginal distributions for Y1A and Y1B are exponential distributions

```

```
# with rate parameters of 0.16 and 0.20, respectively. For Y2A, the marginal
# distribution is a Poisson distribution with a mean of 0.75, and for Y2B, it
# is a normal distribution with a mean of 1.1. The follow-up time for all
# measurements is 5 years.
# Find the achieved power for win ratios with a sample size of 770.
```

```
endpoints_input <- list(
  list(type = "TTE",
        tte.winning.direction = "GT",
        s = 5,
        hr.a = 0.8,
        er.b = 0.63212),
  list(type = "Count",
        count.winning.direction = "LT",
        lam.a = 0.75,
        lam.b = 1.1)
)
HE(endpoints_input,
  sample.size = 770,
  alpha = 0.05,
  rratio = 0.5,
  output = "ALL")
```

```
# Two ordinal hierarchical endpoints, each with 3 ordinal categories:
# The marginal distributions for Y1A and Y1B are multinomial distributions
# with probabilities for the three categories (1, 2, 3) given by
# (0.45, 0.30, 0.25) for Y1A and (0.50, 0.30, 0.20) for Y1B. For Y2A and Y2B,
# the marginal distributions are multinomial distributions with probabilities
# (0.30, 0.30, 0.40) for Y2A and (0.40, 0.30, 0.30) for Y2B. The probabilities
# represent the likelihood of a subject being in categories 1, 2, or 3. We
# assume that a subject in a higher ordinal category wins over a subject in a
# lower ordinal category.
# Find the required sample size to achieve a power of 0.85 for win ratios.
```

```
endpoints_input <- list(
  list(type = "Ordinal",
        pi.ordinal.a = c(0.45, 0.3, 0.25),
        pi.ordinal.b = c(0.5, 0.3, 0.2),
        ordinal.winning.direction = "GT"),
  list(type = "Ordinal",
        pi.ordinal.a = c(0.3, 0.3, 0.4),
        pi.ordinal.b = c(0.4, 0.3, 0.3),
        ordinal.winning.direction = "GT")
)
HE(endpoints_input,
  power = 0.85,
  alpha = 0.05,
  rratio = 0.5,
  output = "ALL")
```

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